**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 510**

**[CMS–5516–F]**

**RIN 0938–AS64**

# Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements a new Medicare Part A and B payment model under section 1115A of the Social Security Act, called the Comprehensive Care for Joint Replacement (CJR) model, in which acute care hospitals in certain selected geographic areas will receive retrospective bundled payments for episodes of care for lower extremity joint replacement (LEJR) or reattachment of a lower extremity. All related care within 90 days of hospital discharge from the joint replacement procedure will be included in the episode of care. We believe this model will further our goals in improving the efficiency and quality of care for Medicare beneficiaries with these common medical procedures.

**DATES:** These regulations are effective on January 15, 2016, and applicable on April 1, 2016 when the first model performance period begins.

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**SUPPLEMENTARY INFORMATION:**

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## Alphabetical List of Acronyms

Because of the many terms to which we refer by acronym, abbreviation, or short form in this final rule, we are listing the acronyms, abbreviations and short forms used and their corresponding terms in alphabetical order.

μSA Micropolitan Statistical Area
ACE Acute Care Episode
ACO Accountable Care Organization
APM Alternative Payment Model
ASC Ambulatory Surgical Center
ASPE Assistant Secretary for Planning and Evaluation
BPCI Bundled Payments for Care Improvement
CAH Critical Access Hospital
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CFR Code of Federal Regulations
CJR Comprehensive Care for Joint Replacement
CMHC Community Mental Health Center
CMI Case Mix Index
CMMI Center for Medicare and Medicaid Innovation
CMP Civil Monetary Penalty
CMS Centers for Medicare & Medicaid Services
CoPs Conditions of Participation
CPCi Comprehensive Primary Care Initiative
CPT Current Procedural Terminology
CSA Combined Statistical Area
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
eCQM Electronic Clinical Quality Measures
EFT Electronic funds transfer
ESRD End-Stage Renal Disease
FFS Fee-for-service
GAAP Generally Accepted Accounting Principles
GEM General Equivalence Mapping
GPCI Geographic Practice Cost Index
HAC Hospital-Acquired Condition
HACRP Hospital-Acquired Condition Reduction Program
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCC Hierarchical Condition Category
HCPCS Healthcare Common Procedure Coding System
HHA Home health agency
HHPPS Home Health Prospective Payment System
HHRG Home Health Resource Group
HHVBP Home Health Value-Based Purchasing
HIT Health Information Technology
HIQR Hospital Inpatient Quality Reporting
HLMR HCAHPS Linear Mean Roll Up
HOOS Hip Dysfunction and Osteoarthritis Outcome Score
HOPD Hospital outpatient department
HRR Hospital Referral Region
HRRP Hospital Readmissions Reductions Program
HVBP Hospital Value Based Purchasing Program
ICD–9–CM International Classification of Diseases, 9th Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, 10th Revision, Clinical Modification
IPPS Inpatient Prospective Payment System
IPF Inpatient psychiatric facility
IRF Inpatient rehabilitation facility
KOOS Knee Injury and Osteoarthritis Outcome Score
LEJR Lower extremity joint replacement
LOS Length of stay
LTCH Long term care hospital
LUPA Low Utilization Payment Adjustment
MAC Medicare Administrative Contractor
MACRA Medicare Access and Chip Reauthorization Act of 2015
MAPCP Multi-Payer Advanced Primary Care Practice model
MCC Major Complications or Comorbidities
MCCM Medicare Care Choices Model
MDH Medicare-Dependent Hospital
MedPAC Medicare Payment Advisory Commission
MIPS Merit-based Incentive Payment System
MP Malpractice
MPFS Medicare Physician Fee Schedule
MSA Metropolitan Statistical Area
MS–DRG Medical Severity Diagnosis-Related Group
NPI National Provider Identifier
NPP Nonphysician Practitioner
NPRA Net Payment Reconciliation Amount
NQF National Quality Forum
OCM Oncology Care Model
OPPS Outpatient Prospective Payment System
PAC Post-Acute Care
PBPM Per Beneficiary Per Month
PE Practice Expense
PGP Physician Group Practice
PHA Partial hip arthroplasty
PPS Prospective Payment System
PRO Patient-Reported Outcome
PROMIS Patient-Reported Outcomes Measurement Information Systems
PRO–PM Patient-Reported Outcome Performance Measure
QIO Quality Improvement Organization
RAC Recovery Audit Contractor
RRC Rural Referral Center
RSCR Risk-Standardized Complication Rate
RSRR Risk-Standardized Readmission Rate
RVU Relative Value Unit
SCH Sole Community Hospital
SNF Skilled nursing facility
THA Total hip arthroplasty
TIN Taxpayer identification number
TKA Total knee arthroplasty
TP Target price
VR–12 Veterans Rand 12 Item Health Survey

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## I. Executive Summary

### *A. Purpose*

The purpose of this final rule is to implement a new payment model called the Comprehensive Care for Joint Replacement (CJR) model under the authority of the Center for Medicare and Medicaid Innovation (CMMI). Section 1115A of the Social Security Act (the Act) authorizes CMMI to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The intent of the CJR model is to promote quality and financial accountability for episodes of care surrounding a lower-extremity joint replacement (LEJR) or reattachment of a lower extremity procedure.[1] CJR will test whether bundled payments to acute care hospitals for LEJR episodes of care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate the CJR model will benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare Fee-For-Service (FFS), encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care (PAC) spectrum spanning the episode of care. We will test the CJR model for 5 performance periods, beginning April 1, 2016, and ending December 31, 2020. Under FFS, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of treatment (an episode of care). With the amount of payments dependent on the volume of services delivered, providers may not have incentives to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative.

We have previously used our statutory authority under section 1115A of the Act to test bundled payment models such as the Bundled Payments for Care Improvement (BPCI) initiative. Bundled payments, for multiple services in an episode of care, hold participating organizations financially accountable for an episode of care. They also allow participants to receive payment, in part, based on the reduction in expenditures for Medicare arising from their care redesign efforts.

We believe the CJR model will further the mission of CMMI and the Secretary's goal of increasingly paying for value rather than for volume,[2] because it will promote the alignment of financial and other incentives for all health care providers and suppliers caring for a beneficiary during an LEJR episode. In the CJR model, the acute care hospital that is the site of surgery will be held accountable for spending during the episode of care. Participant hospitals will be afforded the opportunity to earn performance-based payments by appropriately reducing expenditures and meeting certain quality metrics. They will also gain access to data and educational resources to better understand LEJR patients' PAC needs and associated spending. Payment approaches that reward providers that assume financial and performance accountability for a particular episode of care create incentives for the implementation and coordination of care redesign between hospitals and other providers and suppliers.

The CJR model requires the participation of hospitals in multiple geographic areas that might not otherwise participate in the testing of bundled payments for episodes of care for LEJR procedures. Other episode-based, bundled payment models being tested by the Centers for Medicare & Medicaid Services (CMS), such as the BPCI initiative, are voluntary in nature. Interested participants must apply to such models to participate. To date, we have not tested an episode payment model with bundled payments in which providers are required to participate. We recognize that realizing the full potential of new payment models will require the engagement of an even broader set of providers than have participated to date, providers who may only be reached when new payment models are applied to an entire class of providers of a service. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those hospitals that may not otherwise participate in such a test.

This model will allow CMS to gain experience with making bundled payments to hospitals who have a variety of historic utilization patterns; different roles within their local markets; various volumes of services; different levels of access to financial, community, or other resources; and various levels of population and health provider density including local variations in the availability and use of different categories of PAC providers. We believe that by requiring the participation of a large number of hospitals with diverse characteristics, the CJR model will result in a robust data set for evaluation of this bundled payment approach, and will stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of

[1] In this final rule, we use the term LEJR to refer to all procedures within the Medicare Severity-Diagnosis Related Groups (MS–DRGs) we selected for the model, including reattachment of a lower extremity, as described in section III.B.2.a. of this final rule.

[2] Sylvia Mathews Burwell, *HHS Secretary, Progress Towards Achieving Better Care, Smarter Spending, Healthier People, http://www.hhs.gov/blog/2015/01/26/progress-towards-better-care-smarter-spending-healthier-people.html* (January 26, 2015).

quality for common LEJR procedure episodes. This learning potentially could inform future Medicare payment policy.

This final rule implements a model focused on episodes of care for LEJR procedures. We chose LEJR episodes for the CJR model because as discussed in depth in section III.C. of this final rule, these are high-expenditure, high utilization procedures commonly furnished to Medicare beneficiaries,[3] where significant variation in spending for procedures is currently observed. The high volume of episodes and variation in spending for LEJR procedures create a significant opportunity to test and evaluate the CJR model that specifically focuses on a defined set of procedures. Moreover, there is substantial regional variation in PAC referral patterns and the intensity of PAC provided for LEJR patients, thus resulting in significant variation in PAC expenditures across LEJR episodes initiated at different hospitals. The CJR model will enable hospitals to consider the most appropriate PAC for their LEJR patients. The CJR model additionally will offer hospitals the opportunity to better understand their own processes with regard to LEJR, as well as the processes of post-acute providers. Finally, while many LEJR procedures are planned, the CJR model will provide a useful opportunity to identify efficiencies both for when providers can plan for LEJR procedures and for when the procedure must be performed urgently.

The following is a summary of the comments received on the proposed model as a whole, including the authority for the model and general comments on CMS' implementation of the CJR model at this time and our responses.

*Comment:* A commenter stated that while the proposed rule emphasized the learning CMS hoped to gain from implementing and testing the CJR model, it made inadequate mention of the potential benefits to beneficiaries, providers, hospitals, and other stakeholders. Other commenters contended that bundled payment models encourage hospitals to engage in care stinting and potentially stifle innovation.

*Response:* We appreciate the commenters' concerns. We refer readers to section III.F. of this final rule for discussion of monitoring and beneficiary protections under this model which we believe will address the commenters' concerns about care stinting. We expect that the CJR model will benefit not just CMS, but also beneficiaries, hospitals, and other providers in the health care system. The goals of this model are to improve the quality of care furnished to beneficiaries and reduce spending during LEJR episodes. Beneficiaries would directly benefit from improved care coordination and care redesign activities that reduce readmissions and complications rates, for example, as well as provide an improved care experience during the inpatient hospitalization and post-discharge period. Hospitals also stand to benefit from the CJR model, in the form of the opportunity to earn reconciliation payments if successful under the model, and a structured incentive to redesign care processes for beneficiaries receiving LEJR procedures. For example, section III.C.11. of this final rule details waivers of Medicare program rules that would allow hospitals to test additional ways to introduce flexibility into care processes and improve the quality of care for beneficiaries. In addition, providers and suppliers across the spectrum of care provided during an LEJR episode could also benefit from the care redesign strategies as well as the financial arrangements as detailed in section III.C.10. of this final rule. Finally, we disagree with commenters that the CJR model will stifle innovation for care furnished during an LEJR episode. We proposed, and are finalizing in this final rule, a payment methodology that will account for changes in care patterns and utilization trends for LEJR episodes by updating the historical performance periods used throughout the model, as described in section III.C.4. of this final rule. In addition, the CJR financial incentives would be consistent with clinical practices that result in reductions of spending during LEJR episodes, allowing hospitals that engage in such practices to earn reconciliation payments and engage with other providers furnishing services during the episode, as discussed in section III.C.10. of this final rule.

*Comment:* Several commenters questioned CMS' legal authority to require participation in a model. Commenters stated that CMS lacks the legal authority to compel participation in a model, and that CMS misreads section 1115A(a)(5) of the Act as the legal basis for compelling providers in selected Metropolitan Statistical Area (MSAs) to participate in the CJR model. A commenter stated that language in the Act has never been interpreted to afford the Secretary the authority to compel provider participation in a Medicare demonstration project or model, and that the Congress intended for model tests to be voluntary, not mandatory, when authorizing CMS to test new models. The commenter noted that requiring providers to participate in a model that would encompass a substantial proportion of a particular service would render the statutory distinction between testing and expanding models meaningless. The commenter also expressed concern about the model's potential effect on beneficiaries' appeal rights. Several commenters stated that CMS is sidestepping the legal safeguards designed to prevent the Agency from imposing novel or haphazard models on providers prior to adequate testing and evaluation. Commenters also claimed that CMS had exceeded its statutory authority because under section 1115A of the Act, providers are precluded from appealing their selection in a model, raising further concern that CMS is overreaching by requiring participation in the CJR model. Commenters also noted that there is no precedent for a CMS demonstration or model that requires providers to participate. Finally, several commenters stated that CMS has reversed the intended sequence of testing and then expanding models.

*Response:* We disagree with commenters that we lack the legal authority to test the CJR model as proposed and specifically, to require the participation of selected hospitals. We note that although CJR will be the first Innovation Center model in which acute care hospitals are required to participate, we refer readers to the 2016 Home Health Prospective Payment System (HHPS) Final Rule, which finalizes the Home Health Value-Based Purchasing (HHVBP) model. Home health agencies in selected states will be required to participate in the HHVBP model beginning in January 2016.

We believe that both section 1115A and the Secretary's existing authority to operate the Medicare program authorize the CJR model as we have proposed and are finalizing it. Section 1115A of the Act authorizes the Secretary to test payment and service delivery models intended to reduce Medicare costs while preserving quality. The statute does not

[3] For example, total hip arthroplasty and total knee arthroplasty procedures are very high volume LEJR procedures that together represent the largest payments for procedures under Medicare. Suter L, Grady JL, Lin Z *et al.*: 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*; Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

require that models be voluntary, but rather gives the Secretary broad discretion to design and test models that meet certain requirements as to spending and quality. Although section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, the Secretary is not limited to those models. Rather, models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Here, the CJR model addresses a defined population (FFS Medicare beneficiaries undergoing LEJR procedures) for which there are potentially avoidable expenditures (arising from less than optimal care coordination). For the reasons described elsewhere in this rule, we have determined that it is necessary to test this model among varying types of hospitals that have not chosen to voluntarily participate in another episode payment model such as BPCI. As noted elsewhere in this final rule, we are testing an episode approach for LEJR episodes through the voluntary BPCI models. We have designed the CJR model to require participation by hospitals in order to avoid the selection bias inherent to any model in which providers may choose whether to participate. Such a design will allow for testing of how a variety of hospitals will fare under an episode payment approach, leading to a more robust evaluation of the model's effect on all types of hospitals. We believe this is the most prudent approach for the following reasons. The information gained from testing of the CJR model will allow CMS to more comprehensively assess whether LEJR episode payment models are appropriate for any potential national expansion. We will have evaluation information on results for providers who are participating in such models voluntarily (under BPCI) as well as for hospitals that are required to participate in CJR. Under CJR, we will have tested and evaluated such a model across a wide range of hospitals representing varying degrees of experience with episode payment. We believe it is important to gain knowledge from a variety of perspectives in considering whether and which models merit national expansion. Thus, the CJR model meets the criteria required for initial model tests.

Moreover, the Secretary has the authority to establish regulations to carry out the administration of Medicare. Specifically, the Secretary has authority under both sections 1102 and 1871 of the Act to implement regulations as necessary to administer Medicare, including testing this Medicare payment and service delivery model. We note that while CJR will be a model, and not a permanent feature of the Medicare program, the model will test different methods for delivering and paying for services covered under the Medicare program, which the Secretary has clear legal authority to regulate. The proposed rule went into great detail about the provisions of the proposed CJR model, enabling the public to fully understand how the proposed model was designed and could apply to affected providers. We acknowledge section 1115A(d)(2) of the Act, which states that there shall be no administrative or judicial review of, among other things, ''the selection of organizations, sites, or participants to test . . . models selected,'' as well as the commenter's concern that this provision would preclude a participant hospital from appealing its selection as a participant in the CJR model. However, it is precisely because the model will impose new requirements upon participant hospitals that we undertook notice and comment rulemaking to implement it.

In response to the comment indicating that we misread section 1115A(a)(5) of the Act, we believe that the commenter misunderstood the reference to that provision in the proposed rule. The reference to section 1115A(a)(5) of the Act was made in the context of the discussion of selecting certain MSAs within which we will test the model. We do not rely on section 1115A(a)(5) of the Act specifically as the authority for a model in which participation is not voluntary; rather, as noted previously, we rely on section 1115A of the Act as a whole, as well as the Secretary's existing authority to carry out her duties and administer the Medicare program.

We disagree with commenters that implementing the CJR model will negatively affect beneficiaries' appeal rights. We note that normal claims processes will continue under this model, including beneficiary and provider appeal rights. We also refer readers to section III.C.9. of this final rule for discussion of hospital appeals procedures under the CJR model.

With regard to the comment about CMS sidestepping safeguards designed to prevent imposing haphazard models prior to appropriate vetting and testing, we reiterate that we have undertaken rulemaking to solicit comprehensive public input on all aspects of the CJR model. In addition, as previously noted, the CJR model has been designed to limit selection bias, which will allow for more robust evaluation results across a variety of providers.

We note that this is a new model, not an expansion of an existing model. We disagree with the commenters who believe that we have reversed the order of testing and expansion of Innovation Center models. As permitted by section 1115A of the Act, we are testing the CJR model within specified limited geographic areas. The fact that the model will require the participation of certain hospitals does not mean it is not an initial model test. If the model is successful such that it meets the statutory requirements for expansion, and the Secretary determines that expansion is warranted, we would undertake rulemaking to implement the expansion, as required by section 1115A(c) of the Act.

*Comment:* Several commenters questioned how the proposed CJR model relates to the potential for expansion of BPCI. Commenters also noted that CMS included language in the FY 2016 IPPS/LTCH PPS proposed rule requesting public input on an eventual expansion of BPCI.

*Response:* CMMI's three major priorities include testing new payment and service delivery models, evaluating results and advancing best practices, and engaging stakeholders. Since 2011, we have been working to develop and test models of bundling Medicare payments under the authority of section 1115A of the Act. Consistent with its ongoing commitment to develop new models and refine existing models based on additional information and experience, we may modify existing models or test additional models under our authority under section 1115A of the Act. The CJR model is a new, additional episode payment model being tested under the authority of section 1115A of the Act. As such, it is not an expansion of the BPCI initiative, which needs further evaluation to determine its impact on both Medicare cost and quality before the Secretary can determine whether the findings from the evaluation of the initiative demonstrate that it meets all criteria for expansion, consistent with the requirements of section 1115A(c) of the Act, and that, based on these findings and other pertinent factors, expansion is warranted.

In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24414 through 24418), we solicited public comments regarding policy and operational issues related to a potential expansion of the BPCI initiative in the future. We explained that as we initiated discussions about potential expansion, we continued to value stakeholder

engagement within the framework of our three priorities. With respect to expansion, section1115A(c) of the Act, as added by section 3021 of the Affordable Care Act, provides the Secretary with the authority to expand through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act, such as the BPCI initiative (including implementation on a nationwide basis), if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits. The decision of whether or not to expand BPCI will be made by the Secretary in coordination with CMS and the Office of the Chief Actuary based on whether findings about the initiative meet the statutory criteria for expansion under section 1115A(c) of the Act. We did not propose an expansion of any of the BPCI models or any policy changes associated with those models in the FY 2016 IPPS/LTCH PPS proposed rule.

Although BPCI and the CJR model both include testing episode payment for LEJR episodes of care, CJR differs from BPCI in significant ways, as detailed throughout this final rule. Providers elected to participate in BPCI, and were given a choice of various design features, such as the clinical episodes included and the episode length. The CJR model was designed in part based on feedback and experience from BPCI, and will provide additional information on the impact of episode payment for LEJR episodes across a variety of hospitals, including those who may not have elected to participate in the model. As previously discussed in this section, it is necessary to require participation in the CJR model in order to avoid the selection bias inherent to any voluntary model. When the CJR model begins on April 1, 2016, we will be testing both episode payment models concurrently for a period of time, as well as many other payment and service delivery models, in order to gain information about the most successful strategies to improve the quality of care and reduce spending. The different design features of BPCI and the CJR model will aid us in evaluating the success of episode-based payment across a range of provider types and in a range of geographic areas. As evaluation results addressing the impact of each model on Medicare quality and cost become available, the Secretary will review this information to determine whether the findings from the evaluation of the model demonstrate that it meets all criteria for expansion, consistent with the requirements of section 1115A(c) of the Act, and that, based on these findings and other pertinent factors, expansion is warranted.

*Comment:* Many commenters requested changes to the BPCI model in response to the proposed rule. Commenters also requested clarification on how BPCI awardees would be transitioned into the CJR model; for example, which performance year policies would apply to the new model participants.

*Response:* We will not address comments about BPCI policies in this final rule. We will address commenters' suggestions on BPCI through our usual processes for informing BPCI participants and the public of any changes to BPCI. As discussed in section III.A of this final rule, all Inpatient Prospective Payment System (IPPS) hospitals in the selected MSAs that are not participating in BPCI Model 1 or Phase II of Models 2 or 4 for LEJR episodes would be included in the CJR model. We intend for the current performance year's policies to be in effect for any new entrants in the CJR model. We also note that an acute care hospital formerly participating in BPCI for the LEJR episode will have likely established care coordination and redesign strategies for success. As such, it would not be necessary to grant such hospitals additional time to transition from BPCI into the CJR model.

*Comment:* Numerous commenters requested that physicians who enter into sharing arrangements with CJR hospitals qualify as eligible professionals under the Medicare Access and Chip Reauthorization Act of 2015 (MACRA) beginning in 2019. A commenter requested that all CJR collaborators qualify as eligible professionals under MACRA. Several commenters outlined wholly different structures for the proposed CJR model, including provisions that would allow for the CJR model to qualify as an alternative payment model (APM) under MACRA.

*Response:* We interpret commenters' requests as follows: That collaborators under the CJR model would be able to meet the requirements that would otherwise apply under the Merit-based Incentive Payment System (MIPS) or, alternatively, qualify as APM participants under section 1833(z)(2) of the Act (and therefore be excluded from MIPS) through their participation in CJR. We further interpret commenters' requests as follows: That CJR would include eligible alternative payment entities, and therefore that eligible professionals in CJR would potentially be qualifying APM participants. We note that the statute specifies which types of individuals qualify as eligible professionals (EPs) under section 1848(k)(3)(B) of the Act or as MIPS EPs under section 1848(q)(1)(C) of the Act. We plan to develop regulations under MACRA through notice and comment rulemaking. We will be releasing further guidance on the implementation of MACRA, and through such guidance, will be clarifying the parameters for eligibility under MACRA.

*Comment:* Several commenters presented different episode payment models for CMS' consideration to be tested in addition to or instead of the CJR model, or suggested such major changes to the proposed CJR model design elements that the result of their adoption would be a wholly different test of episode payment than CMS proposed. A few commenters recommended that CMS consider testing a model that emphasizes the role of PAC providers in managing episode care for beneficiaries, instead of just the hospital. Such a model would assign financial responsibility during an episode to a PAC entity with capabilities to coordinate care across a wide range of post-acute settings. Other commenters suggested that CMS test a model that would create physician-led organizations to manage financial risk for LEJR episodes of care, instead of assigning risk to hospitals. These organizations would receive prospective episodic payments and allocate such payments among the providers and suppliers furnishing care to beneficiaries during an LEJR episode. Several commenters recommended CMS implement a population-based model similar to an Accountable Care Organization (ACO) model, in lieu of an episode-based payment model. Finally, a commenter requested that instead of including rural and low-volume hospitals in the CJR model, CMS develop a model tailored to this subset of providers.

*Response:* We appreciate the suggestions for alternatives to the CJR model design that were recommended by the commenters, including the details and rationale provided about many features of those models. We are

not adopting these approaches to an episode payment model under this final rule as we did not propose the design elements of such models for public notice and comment nor did we propose the additional policies that would be required to implement such features that do not rely on existing Medicare definitions (for example, the definition of a physician-led organization to manage risk). However, we note that we are constantly considering modifications to existing models and designing new models under our testing authority under section 1115A of the Act, taking into consideration stakeholder input received through many channels, including public comments on this proposed rule and the FY 2016 IPPS/LTCH PPS proposed rule discussion item on potential BPCI expansion considerations, as well as feedback from providers participating in existing models. We note that potential modifications to the CJR model would go through notice and comment rulemaking as necessary. As we consider developing additional payment service and delivery models, we will continue to engage with stakeholders and review all of the information available to us about alternative approaches to episode payment that could be tested.

*B. Summary of the Major Provisions*

1. Model Overview: LEJR Episodes of Care

LEJR procedures are currently paid under the IPPS (IPPS) through one of two Medicare Severity-Diagnosis Related Groups (MS–DRGs): MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) or MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC). Under the CJR model, as described further in section III.B of this final rule, episodes will begin with admission to an acute care hospital for an LEJR procedure that is assigned to MS–DRG 469 or 470 upon beneficiary discharge and paid under the IPPS and will end 90 days after the date of discharge from the acute care hospital. This episode of care definition offers operational simplicity for providers and CMS. The episode will include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, PAC, and physician services.

2. Model Scope

We have finalized that participant hospitals will be the episode initiators and bear financial risk under the CJR model. In comparison to other health care facilities, hospitals are more likely to have resources that will allow them to appropriately coordinate and manage care throughout the episode, and hospital staff members are already involved in hospital discharge planning and PAC recommendations for recovery, key dimensions of high quality and efficient care for the episode. We require all hospitals paid under the IPPS in selected geographic areas to participate in the CJR model, with limited exceptions. Eligible beneficiaries who elect to receive care at these hospitals will automatically be included in the model. We have selected geographic areas based on a stratified random sampling methodology within strata using the following criteria: historical wage adjusted episode payments and population size. Our geographic area selection process is detailed further in section III.A of this final rule.

3. Payment

We will test the CJR model for 5 performance years. We have finalized an alternative start date for the model from the timeline set forth in the proposed rule. As discussed in further detail in section III.C.2.a. of this final rule, the first performance year for the CJR model will begin on April 1, 2016 and end on December 31, 2016. During these performance years we will continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, will be combined to calculate an actual episode payment. The actual episode payment is defined as the sum of related Medicare claims payments for items and services furnished to a beneficiary during a CJR episode. The actual episode payment will then be reconciled against an established CJR target price that is stratified based on the beneficiary's fracture status, with consideration of additional payment adjustments based on quality performance, post-episode spending, and policies to limit hospital financial responsibility. The amount of this calculation, if positive, will be paid to the participant hospital. This payment will be called a reconciliation payment. If negative, we will require repayment from the participant hospital. Medicare will require repayment of the difference between the actual episode payments and the CJR target price from a participant hospital if the CJR target price is exceeded.

We will make reconciliation payments to participant hospitals that achieve quality outcomes and cost efficiencies relative to the established CJR target prices in all performance years of the model. We will also phase in the requirement that participant hospitals whose actual episode payments exceed the applicable CJR target price pay the difference back to Medicare beginning in performance year 2. Under this final rule, Medicare will not require repayment from hospitals for performance year 1 for actual episode payments that exceed their target price in performance year 1.

We will also limit how much a hospital can gain or lose based on its actual episode payments relative to target prices. We have also put in place additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of participant hospitals as described in section III.C. of this final rule.

4. Similar, Previous, and Concurrent Models

The CJR model is informed by other models and demonstrations currently and previously conducted by CMS and will explore additional ways to enhance coordination of care and improve the quality of services through bundled payments. We recently announced the Oncology Care Model (OCM), a new voluntary payment model for physician practices administering chemotherapy. Under OCM, practices will enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. We plan to coordinate with other payers to align with OCM in order to facilitate enhanced services and care at participating practices. More information on the OCM can be found on CMMI's Web site at: *http://innovation.cms.gov/initiatives/Oncology-Care/*. Medicare tested innovative approaches to paying for orthopedic services in the Medicare Acute Care Episode (ACE) demonstration, a prior demonstration, and is currently testing additional approaches under BPCI. Both of these models have also informed the design of the CJR model.

Under the authority of section 1866C of the Act, we conducted a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode

of care was defined as a combination of Part A and Part B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS–DRGs. The MS–DRGs tested included 469 and 470, which are included in the CJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After accounting for increased PAC costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending. More information on the ACE Demonstration can be found on CMMI's Web site at: *http://innovation.cms.gov/initiatives/ACE/*.

We are currently testing the BPCI initiative. The BPCI initiative is comprised of four related payment models, which link payments for multiple services that Medicare beneficiaries receive during an episode of care into a bundled payment. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either—(1) An inpatient hospital stay; or (2) PAC services following a qualifying inpatient hospital stay. The BPCI initiative is evaluating the effects of episode-based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Each of the four models tests LEJR episodes of care. While final evaluation results for the models within the BPCI initiative are not yet available, we believe that CMS' experiences with BPCI support the design of the CJR model. Under section 1115A(c) of the Act, the Secretary may, taking into consideration an evaluation conducted under section 1115A (b)(4) of the Act, ''through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under'' CMMI's authority. CJR is not an expansion of BPCI, and BPCI may be expanded in the future. We published a discussion item soliciting public comment on a potential future expansion of one or more of the models within BPCI in the FY2016 IPPS rule, 80 FR 24414 through 24418. CJR will not be an expansion or modification of BPCI; nor does it reflect comments received in response to the proposed rule for the 2016 IPPS Rule. CJR is a unique model that tests a broader, different group of hospitals than BPCI. It is necessary to provide CMS with information about testing bundled payments to hospitals that are required to participate in an APM. For a discussion of why we are requiring hospitals to participate in the CJR model, see section III.A. of this final rule.

The CJR model's design was informed to a large degree by our experience with BPCI Model 2. BPCI's Model 2 is a voluntary episode payment model in which a qualifying acute care hospitalization initiates a 30, 60 or 90 day episode of care. The episode of care includes the inpatient stay in an acute care hospital and all related services covered under Medicare Parts A and B during the episode, including PAC services. More information on BPCI Model 2 can be found on CMMI's Web site at: *http://innovation.cms.gov/initiatives/BPCI-Model-2/*.

Further information of why elements of the OCM, the ACE Demonstration, and BPCI Model 2 were incorporated into the design of the CJR model appears later in this final rule.

5. Overlap With Ongoing CMS Efforts

We are excluding from participation in CJR certain hospitals participating in the risk-bearing phase of BPCI Models 2 and 4 for LEJR episodes, as well as acute care hospitals participating in BPCI Model 1. We are not excluding beneficiaries in CJR model episodes from being included in other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program (Shared Savings Program), as detailed later in this final rule. We will account for overlap, that is, where CJR beneficiaries are also included in other models and programs, to ensure the financial policies of CJR are maintained and results and spending reductions are attributed to the correct model or program.

6. Quality Measures and Reporting Requirements

We are adopting two hospital-level quality of care measures for the CJR model. Those measures include a complications measure and a patient experience survey measure. We will use these measures in the model pay-for-performance payment methodology, as well as to test the success of the model in achieving its goals under section 1115A of the Act and to monitor for beneficiary safety. We intend to publicly report this information on the *Hospital Compare* Web site. Additionally, we will encourage the voluntary submission of data to support the development of a hospital-level measure of patient-reported outcomes following an elective primary total hip (THA) or total knee arthroplasty (TKA) through incorporation of the measure in the composite quality scoring methodology described in III.C.5. of this final rule.

7. Data Sharing Process

We will share data with participant hospitals upon request throughout the performance period of the CJR model to the extent permitted by the HIPAA Privacy Rule and other applicable law. We will share upon request both raw claims-level data and claims summary data with participants. This approach will allow participant hospitals without prior experience analyzing claims to use summary data to receive useful information, while allowing those participant hospitals who prefer raw claims-level data the opportunity to analyze claims. We will provide hospitals with up to 3 years of retrospective claims data upon request that will be used to develop their target price, as described in section III.C. of this final rule. In accordance with the HIPAA Privacy Rule, we will limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population.

8. Beneficiary Protections

Under the CJR model, beneficiaries retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Under the CJR model, eligible beneficiaries who receive services from a participant hospital will not have the option to opt out of inclusion in the model. We require participant hospitals to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice. We will also make a robust effort to reach out to beneficiaries and their advocates to help them understand the CJR model.

We also will use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. Beneficiary protections are discussed in greater depth in section III.E. of this final rule.

9. Financial Arrangements and Program Policy Waivers

We will hold participant hospitals financially responsible for CJR LEJR episodes as participants in the model as discussed in section III.C.6. of this final

rule. Specifically, only these hospital participants will be directly subject to the requirements of this final rule for the CJR model. Participant hospitals will be responsible for ensuring that other providers and suppliers collaborating with the hospital on LEJR episode care redesign are in compliance with the terms and conditions of the model, including any applicable program policy waivers.

Several of the Medicare program policy waivers outline the conditions under which SNFs and physicians could furnish and bill for certain services furnished to CJR beneficiaries where current Medicare programs rules will not permit such billing. We draw the attention of SNFs and physicians to these waivers, which are included in section III.C.11.b.(5). of this final rule.

*C. Summary of Economic Effects*

As shown in our impact analysis, we expect the CJR model to result in savings to Medicare of $343 million over the 5 performance years of the model. We note that a composite quality score will be calculated for each hospital in order to determine eligibility for a reconciliation payment and whether the hospital qualifies for quality incentive payments that will reduce the effective discount percentage experience by the hospital at reconciliation for a given performance year.

More specifically, in performance year 1 of the model, we estimate a Medicare cost of approximately $11 million, as hospitals will not be subject to downside risk in the first year of the model. As we introduce downside risk beginning in performance year 2 of the model, we estimate Medicare savings of approximately $36 million. In performance year 3 of the model, we estimate Medicare savings of $71 million. In performance years 4 and 5 of the model, we will move from target episode pricing that is based on a hospital's experience to target pricing based on regional experience, we estimate Medicare savings of $120 million and $127 million, respectively.

As a result, we estimate the net savings to Medicare to be $343 million over the 5 performance years of the model. We anticipate there will be a broader focus on care coordination and quality improvement for LEJR episodes among hospitals and other providers and suppliers within the Medicare program that will lead to both increased efficiency in the provision of care and improved quality of the care provided to beneficiaries.

We note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking as necessary.

## II. Background

*A General Background*

This final rule finalizes the implementation of a new innovative health care payment model under the authority of section 1115A of the Act. Under the model, called the CJR model, acute care hospitals in certain selected geographic areas will receive bundled payments for episodes of care where the diagnosis at discharge includes a lower extremity joint replacement (LEJR) or reattachment of a lower extremity that was furnished by the hospital. The bundled payment will be paid retrospectively through a reconciliation process; hospitals and other providers and suppliers will continue to submit claims and receive payment via the usual Medicare FFS payment systems. All related care covered under Medicare Part A and Part B within 90 days after the date of hospital discharge from the joint replacement procedure will be included in the episode of care. We believe this model will further our goals of improving the efficiency and quality of care for Medicare beneficiaries for these common medical procedures.

*B. Acronym of This Model*

We have changed the acronym of this model to ''CJR'' and have updated all references in this rule and the regulations to reflect this change.

*C. Public Comments Received in Response to the CJR Proposed Rule*

We received approximately 400 timely pieces of correspondence containing multiple comments on the CJR proposed rule. We note that some of these public comments were outside of the scope of the proposed rule. These out-of-scope public comments are mentioned but not addressed with the policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

## III. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

*A. Definition of the Episode Initiator and Selected Geographic Areas*

1. Background

The CJR model is different from BPCI because it would require participation of all hospitals (with limited exceptions) throughout selected geographic areas, which would result in a model that includes varying hospital types. However, a discussion of BPCI is relevant because its design informs and supports the proposed CJR model. The BPCI model is voluntary, and under that model we pay a bundled payment for an episode of care only to entities that have elected to participate in the model. We are interested in testing and evaluating the impact of an episode payment approach for LEJRs in a variety of other circumstances, including among those hospitals that have not chosen to voluntarily participate because we have not tested bundled payments for these hospitals previously. This would allow CMS and participants to gain experience testing and evaluating episode-based payment for LEJR procedures furnished by hospitals with a variety of historic utilization patterns; roles within their local markets; volume of services provided; access to financial, community, or other resources; and population and health care provider density. Most importantly, participation of hospitals in selected geographic areas will allow CMS to test bundled payments without introducing selection bias such as the selection bias inherent in the BPCI model due to self-selected participation.

2. Definition of Episode Initiator

Under the CJR model, as described further in section III.B. of this final rule, episodes will begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through Medical Severity Diagnosis-Related Group (MS–DRG) 469 (Major joint replacement or reattachment of lower extremity with MCC) or 470 (Major joint replacement or reattachment of lower extremity without MCC) and end 90 days after the date of discharge from the hospital. For the CJR model, we proposed that hospitals would be the only episode initiators. For purposes of CJR, the term ''hospital'' means a hospital as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS. We proposed that all acute care hospitals in Maryland would be

excluded from CJR. The state of Maryland entered into an agreement with CMS, effective January 1, 2014, to participate in CMS' new Maryland All-Payer Model. In order to implement the Maryland All-Payer Model, CMS waived certain requirements of the Act, and the corresponding implementing regulations, as set forth in the agreement between CMS and Maryland. Specifically, under the Maryland All-Payer Model, Maryland acute care hospitals are not paid under the IPPS or Outpatient Prospective Payment System (OPPS) but rather are paid under rates set by the state. Following the model's performance period, Maryland will transition to a new model that incorporates the full spectrum of care, not just hospital services. As such, with respect to Maryland hospitals, CMS intends to test and develop new payment and delivery approaches that can incorporate non-hospital services in a manner that accounts for Maryland's unique hospital rate setting system and permit Maryland to develop its own strategy to incentivize higher quality and more efficient care across clinical situations within and beyond hospitals, including but not limited to LEJR episodes of care. We proposed that because Maryland hospitals are not paid under the IPPS or OPPS, payments to Maryland hospitals will be excluded in the regional pricing calculations as described in section III.C.4. of this final rule. We sought comment on whether there were potential approaches for including Maryland acute care hospitals in CJR. In addition, we sought comment on whether Maryland hospitals should be included in CJR in the future upon any termination of the Maryland All-Payer Model.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters commented on the proposed exclusion of Maryland hospitals in the All-Payer model from the model. A commenter requested that if we are considering approaches for including Maryland acute care hospitals in the CJR model that we ensure that the inclusion of such hospitals would not jeopardize the current all-payer system in Maryland. If such an approach were to be developed, the commenter noted that it would welcome the opportunity to participate in the CJR model and further stated that it is confident that it would be successful under the CJR model in helping to further to goals of providing high quality care at lower costs to better patient outcomes and population health. Another commenter noted that Maryland's All-Payer Model Agreement is focused on holding hospitals accountable for improving care, improving health, and reducing the total cost of hospital care for all payers. Under the All-Payer model, Maryland has shifted its long-standing hospital rate-setting system from a volume-based system, focused on cost per case, to a global population-based system that incorporates performance requirements for quality and outcomes. The Maryland system will be held accountable for the total cost of care for Medicare patients under its contract with CMS and thus already has two-sided risk for hospital costs. The commenter stated that Maryland wants to work with CMS to develop a unique approach to achieving the goals of the model, but under the All-Payer model. Lastly, another commenter expressed confusion if we were announcing a plan to have Maryland transition to a new model that incorporates the full spectrum of care, not just hospital services.

*Response:* Under the All-Payer model, Maryland has facilitated the movement of regulated hospital revenue into population-based payment reimbursement under a hospital global budget model. We appreciate the state's efforts to move away from volume-based payments and to focus on reducing total cost of care and improving quality of care, and we have seen improvement on these areas in the first year of the All-Payer model. However, we remain concerned that certain aspects of the All-Payer Model make it challenging for Maryland to be included in other payment and delivery innovations being launched by the CMS Innovation Center. As we anticipate testing more models across the country, we do not want Maryland to fall behind in payment and delivery innovation. We are very interested in Maryland's strategy to be accountable for total cost of care beyond hospital services, which we intend to implement under the All-Payer model in 2019. We note that we are not announcing a new model for Maryland in this rule, but rather the CMS Innovation Center looks forward to working with Maryland on its total cost of care model.

*Comment:* Several commenters agreed with CMS that Maryland hospitals should not be included in our definition of ''hospital'' and, instead, the state of Maryland should be allowed to develop its own strategy to encourage higher quality care and efficiencies across clinical settings.

*Response:* We agree that for the purposes of the CJR model, the term ''hospital'' should only encompass hospitals currently paid under the IPPS and we are finalizing as proposed to exclude Maryland hospitals from the CJR model.

*Final Decision:* After consideration of the public comments we received, we are finalizing, for purposes of the CJR model, the term ''hospital'' to mean a hospital subject to the IPPS as defined in section 1886(d)(1)(B) of the Act. This statutory definition of hospital includes only acute care hospitals paid under the IPPS, thus excluding Maryland hospitals from participating in CJR and excluding payments to Maryland hospitals in regional pricing calculations described in section III.C.4 of this final rule. This definition will be codified in § 510.2

We proposed to designate IPPS hospitals as the episode initiators to ensure that all Medicare FFS LEJR services furnished by participant hospitals in selected geographic areas to beneficiaries who do not meet the exclusion criteria (specified in section III.B.3. and section III.C.7. of this final rule) are included in the CJR model. Given that our proposal that the LEJR episode begins with an admission to a hospital paid under the IPPS that results in a discharge assigned to MS–DRG 469 or 470, we further believed that utilizing the hospital as the episode initiator is a straightforward approach for this model because the hospital furnishes the LEJR procedure. In addition, we noted our interest in testing a broad model in a number of hospitals under the CJR model in order to examine results from a more generalized payment model. Thus, we believed it is important that, in a model where hospital participation is not voluntary, all Medicare FFS LEJR episodes that begin at the participant hospital in a selected geographic area should be included in the model for beneficiaries that do not meet the exclusion criteria specified in section III.B.3. of this final rule and are not LEJR BPCI episodes that we are excluding as outlined in this section and also in section III.C.7 of this final rule. This is best achieved if the hospital is the episode initiator. Finally, as described in the following sections that present our proposed approach to geographic area selection, this geographic area selection approach relies upon our definition of hospitals as the entities that initiate episodes. We sought comment on our proposal to define the episode initiator as the hospital under CJR. However, commenters generally commented on our proposal to define the episode initiator as the hospital in tandem with comments regarding the proposal that the hospital also be the entity financially responsible for the episode of care under CJR. As such, comments regarding the proposed

episode initiator and the entity financially responsible for the episode of care are summarized in section III.A.2. of this final rule.

3. Financial Responsibility for the Episode of Care

BPCI Model 2 participants that have entered into agreements with CMS to bear financial responsibility for an episode of care include acute care hospitals paid under the IPPS, health systems, physician-hospital organizations, physician group practices (PGPs), and non-provider business entities that act as conveners by coordinating multiple health care providers' participation in the model. Thus, our evaluation of BPCI Model 2 will yield information about how results for LEJR episodes may differ based on differences in which party bears financial responsibility for the episode of care. For the CJR model, we proposed to make hospitals financially responsible for the episode of care.

Although we proposed that hospitals would bear the financial responsibility for LEJR episodes of care under CJR, because there are LEJR episodes currently being tested in BPCI Model 1, 2, 3 or 4, we believed that participation in CJR should not be required if it would disrupt testing of LEJR episodes already underway in BPCI models. Therefore, we proposed certain exceptions for instances where IPPS hospitals located in an area selected for the model are active participant hospitals or episode initiators for LEJR episodes as of July 1, 2015, and exceptions for LEJR episodes initiated by other providers or suppliers under certain BPCI models.

The following is a summary of the comments received and our responses.

*Comment:* Most commenters expressed overall support for the CJR model, with some commenters noting that the CJR model could help to transform care delivery through improved care coordination and financial accountability. Several commenters further expressed support for our proposal to designate hospitals as the episode initiators and the entity financially responsible for the episode of care under the CJR model. These commenters agreed that hospitals should bear the responsibility of implementing the CJR model and further agreed with being able to share this responsibility with ''collaborators'' through gainsharing agreements. The commenters noted that the themes surrounding responsibility and cost in conjunction with quality as presented in the proposed rule were encouraging and show a continued focus on bettering outcomes and patient engagement while lowering costs.

*Response:* We thank the commenters for their support. As noted in the proposed rule, the intent of the CJR model is to promote quality and financial accountability for episodes of care surrounding a lower-extremity joint replacement (LEJR) or reattachment of a lower extremity procedure. We anticipate the CJR model would benefit Medicare beneficiaries by improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and PAC spectrum spanning the episode of care (80 FR 41198).

*Comment:* Several commenters disagreed with the proposal for the CJR model to limit financial responsibility for the episode of care to only hospitals. Commenters advocated for PGPs or orthopedic surgeons to be financially responsible, while other commenters advocated for PAC entities to be financially responsibility for the episode of care. Commenters listed a variety of reasons why orthopedic physician groups and/or PAC providers should be financially responsible for the episode of care. Some commenters stated that the episode initiator for the CJR model should be a physician, as key clinical decisions about care within the episode are made by physicians, including determining what kind of follow-up care is needed. A few commenters stated that the episode initiator should be the PAC provider, similar to BPCI Model 3, since much of the reduction in CJR episode costs could occur through changes in PAC utilization. A few commenters stated that CMS should distribute program risk across all providers within the episode of care and not delegate that function to the hospital because during a CJR episode, ideal care and successful care coordination involve multiple providers across the care continuum and is especially dependent on PAC providers. Finally, several commenters stated that with gainsharing there is greater opportunity for the physician to participate in patient care redesign, but that unless the physician is also financially responsible, physician involvement in the full care redesign would be less than ideal.

*Response:* As noted in the proposed rule (80 FR 41204 through 41205), because the CJR model is testing a more generalizable model by including providers that might not participate in a voluntary model, we believe it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the CJR model as one entity needs to be ultimately responsible for ensuring that care for CJR model beneficiaries is appropriately furnished and coordinated in order to avoid fragmented approaches that are often less effective and more costly. Hospitals play a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing LEJR procedures. Most hospitals already have some infrastructure in place related to patient and family education and health information technology as hospitals receive incentive payments for the adoption and meaningful use of interoperable health information technology (HIT) and qualified electronic health records (EHRs). In addition, hospitals are required by the hospital Conditions of Participation (CoPs) to have in effect a discharge planning process that applies to all patients (§ 482.43). As part of the discharge planning process, hospitals are required to arrange for the initial implementation of the discharge plan (§ 482.43(c)(3)), which includes coordinating with PAC providers, a function usually performed by hospital discharge planners or case managers. Thus hospitals can build upon already established infrastructure, practices, and procedures to achieve efficiencies under this episode payment model. Many hospitals also have recently heightened their focus on aligning their efforts with those of community providers to provide an improved continuum of care due to the incentives under other CMS models and programs, including ACO initiatives such as the Medicare Shared Savings Program, and the Hospital Readmissions Reduction Program (HRRP), establishing a base for augmenting these efforts under the CJR model. Hospitals are also more likely than other providers and suppliers to have an adequate number of episode cases to justify an investment in episode management for this model, have access to resources that would allow them to appropriately manage and coordinate care throughout the LEJR episode, and hospital staff is already involved in discharge planning and placement recommendations for Medicare beneficiaries, and more efficient PAC service delivery provides substantial opportunities for improving quality and reducing costs under CJR.

We considered requiring treating physicians (orthopedic surgeons or

others) or their associated PGPs, if applicable, to be financially responsible for the episode of care under the CJR Model. However, the services of providers and suppliers other than the hospital where the acute care hospitalization for the LEJR procedure occurs would not necessarily be furnished in every LEJR episode. For example, that physicians of different specialties play varying roles in managing patients during an acute care hospitalization for a surgical procedure and during the recovery period, depending on the hospital and community practice patterns and the clinical condition of the beneficiary and could not be assumed to be included in every LEJR episode. This variability would make requiring a particular physician or PGP to be financially responsible for a given episode very challenging. If we were to assign financial responsibility to the operating physician, it is likely that there would be significant variation in the number of relevant episodes that could be assigned to an individual person. Where the physician was included in a PGP, episodes could be aggregated to this group level but this would not be possible for all cases and would likely still have multiple instances with physicians with a very low volume of cases. We acknowledge that providers and suppliers with low volumes of cases may not find it in their financial interests to make systematic care redesigns or engage in an active way with the CJR model. We expect that low volume hospitals may achieve less savings compared to their target episode payments for the simple reason that they would not find the financial incentive present in the CJR sufficiently strong to cause them to shift their practice patterns. While this concern is present in low volume hospitals, it is much more likely to occur if physicians are financially responsible for episode costs because physicians typically do not have the case volume to justify an investment in the infrastructure needed to adequately provide the care coordination services required under the CJR model (such as dedicated support staff for case management), which leads us to believe that as a result, the model would be less likely to succeed.

Although the BPCI initiative allows a PGP and PAC providers to have financial responsibility for episodes of care, the physician groups and PAC providers electing to participate in BPCI have done so because their business structure supports care redesign and other infrastructure necessary to bear financial responsibility for episodes and is not necessarily representative of the typical group practice or PAC provider. Most of the PGPs in BPCI are not bearing financial responsibility, but are participating in BPCI as partners with convener organizations, which enter into agreements with CMS on behalf of health care providers, through which they accept financial responsibility for the episode of care. The PAC providers in BPCI are not at risk for episodes that include more than just the post-anchor hospital discharge period. The incentive to invest in the infrastructure necessary to accept financial responsibility for the entire CJR episode of care, starting at admission to an acute care hospital for an LEJR procedure that is paid under the IPPS MS–DRG 469 or 470 and ending 90 days after the date of discharge from the hospital, would not be present across all PGPs and PAC providers. Thus we do not believe it would be appropriate to designate PGPs or PAC providers to bear the financial responsibility for making repayments to CMS under the CJR model where participation is mandatory, rather than voluntary in nature, potentially causing this model to be less likely to succeed. We may consider, through future rulemaking, other episode of care models in which PGPs or PAC providers are financially responsible for the costs of care.

*Comment:* Several commenters suggested that conveners—non-provider business entities that coordinate multiple health care providers' participation in the model—should also be allowed to bear financial responsibility for episodes of care under the proposed CJR model. A commenter suggested that instead of making hospitals responsible for managing payments and costs, a management organization should be designated or created to manage the costs and payments.

*Response:* In the BPCI initiative, participants have entered into a variety of relationships with entities above the hospital level. Some of these relationships are ones where the financial responsibility is borne by an entity other than the hospital, such as a parent organization (known as awardee conveners). Other relationships between hospitals and other organizations (known as facilitator conveners) are more managerial or consultative where financial responsibility remains with the episode initiator (for example, the hospital). We acknowledge the important role that conveners play in the BPCI initiative with regard to providing infrastructure support to hospitals and other entities initiating episodes in BPCI. The convener relationship (where another entity assumes financial responsibility) may take numerous forms, including contractual (such as a separate for-profit company that agrees to take on a hospital's financial risk in the hopes of achieving financial gain through better management of the episodes) and through ownership (such as when financial responsibility is borne at a corporate level within a hospital chain). However, we proposed that for the CJR model we would hold only the participant hospitals financially responsible for the episode of care. This is consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based reimbursement arrangements. If conveners were included as participants in CJR, we may not gain the knowledge of how a variety of hospitals can succeed in relationship with CMS in which they bear financial risk for the episode of care.

While we proposed that the participant hospital be financially responsible for the episode of care under CJR, we agreed that effective care redesign for LEJR episodes requires meaningful collaboration among acute care hospitals, PAC providers, physicians, and other providers and suppliers within communities to achieve the highest value care for Medicare beneficiaries. We believe it may be essential for key providers and suppliers to be aligned and engaged, financially and otherwise, with the hospitals, with the potential to share financial responsibility with those hospitals. As such, CJR participant hospitals may enter into relationships with other entities in order to manage the episode of care or distribute risk. We refer readers to section III.C.10 of this final rule for further discussion of financial arrangements between participant hospitals and other providers and suppliers. Depending on a hospital's current degree of clinical integration, new and different contractual relationships among hospitals and other health care providers and suppliers may be important, although not necessarily required, for CJR model success in a community. We acknowledge that financial incentives for other providers and suppliers may be important aspects of the model in order for hospitals to partner with these providers and suppliers and incentivize certain strategies to improve episode efficiency.

As noted in the proposed rule (80 FR 41261), in addition to providers and

suppliers with which the participant hospital may want to enter into financial arrangements to share risks and rewards, we expect that participant hospitals may choose to engage with organizations that are neither providers nor suppliers to assist with matters such as: Episode data analysis; local provider and supplier engagement; care redesign planning and implementation; beneficiary outreach; CJR beneficiary care coordination and management; monitoring participant hospital compliance with the terms and conditions of the CJR model; or other model-related activities. These organizations may play important roles in a hospital's plans to implement the CJR model based on the experience these organizations may bring to the hospital's successful participation in the model, such as prior experience with bundled payment initiatives, care coordination expertise, familiarity with the local community, and knowledge of Medicare claims data. All relationships established between participant hospitals and these organizations for purposes of the CJR model would only be those permitted under existing law and regulation, meaning that gainsharing agreements between hospitals and organizations that are neither providers nor suppliers are not permitted. Hospital relationships with organizations other than providers and suppliers would be based solely on the ability of such organizations to directly support the participant hospitals' CJR model implementation.

*Comment:* Numerous commenters urged CMS to implement the CJR model on a voluntary basis, rather than requiring hospitals to participate. Commenters observed that the CJR model was unprecedented, unjustified, and risky for beneficiaries, because it was the first time CMS would require participation of providers who may not have the interest, experience, capability, or infrastructure to carry out what is necessary for an experiment whose outcomes are unknown. Other commenters claimed that some of the hospitals in the selected MSAs would not be prepared for model participation due to a lack of resources to better coordinate care, insufficient infrastructure, low patient volumes, and lack of negotiating power in their communities, among other reasons. A few commenters disagreed with designating hospitals as financially responsible for the episode of care under CJR if the hospital cannot withdraw its participation if it cannot thrive under the model. The commenters stated that absent readmissions, hospitals have limited influence over other, non-surgical costs associated with joint replacements, such as PAC, rehabilitation, home care, doctors' visits, and more. Conversely, a commenter wrote that there may be some hospitals not in the selected MSAs that would like to participate in CJR and would be precluded from doing so unless CMS opens the model to other hospitals who volunteered to participate. Several commenters requested that CMS continue to test voluntary payment models so that providers can continue to tailor bundled payment reforms to their particular patient populations, practice settings, markets, infrastructure, and administrative resources. A commenter stated that requiring participation in the CJR model may preclude testing of alternative, potentially more effective, approaches. Another commenter contended that requiring participation in this model for providers who may also be participating in a voluntary payment model could create confusion and competing incentives. Commenters further questioned the appropriateness of requiring participation in CJR, given that hospitals may not have contractual agreements with other providers and suppliers furnishing services during an episode. Finally, several commenters contended that the CJR model could result in beneficiary harm; a commenter stated that because participation in the CJR model is required, CMS should be held responsible for any harm to beneficiaries as a result of the model.

*Response:* We appreciate the views of the commenters on our proposal for required participation in the CJR model test of LEJR episode payment. We recognize that the CJR model represents the first time the Innovation Center will require hospital participation in a payment model being tested under section 1115A of the Act, and we have engaged in rulemaking to ensure robust opportunity for public notice and comment on the model and its design. This model will allow CMS to gain experience with making bundled payments to hospitals who have a variety of historic utilization patterns; different roles within their local markets; various volumes of services; different levels of access to financial, community, or other resources; and various levels of population and health provider density including local variations in the availability and use of different categories of PAC providers. We believe that by requiring the participation of a large number of hospitals with diverse characteristics, the CJR model will result in a robust data set for evaluation of this bundled payment approach, and will stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for common LEJR procedure episodes. Finally, requiring participation removes selection bias and gives CMS a better, more accurate picture of the effects of the model for consideration of any potential expansion on a national scale.

We have multiple years of experience with several types of large voluntary episode payment models where we have successfully collaborated with participants on implementation of episode payment in a variety of settings for multiple clinical conditions. We believe the relatively narrow scope of the model (LEJR episodes only), the phasing in of full financial responsibility over multiple years of the model, and our plan to engage with hospitals to help them succeed under this model through the provision of claims data, will aid hospitals in succeeding under the CJR model. As discussed in section III.C.2. of this final rule, we are also finalizing that the model's first performance period will begin April 1, 2016, instead of on January 1, 2016 as originally proposed. The longer notice of the final model policies before implementation will provide hospitals with more time to prepare for participation by identifying care redesign opportunities, beginning to form financial and clinical partnerships with other providers and suppliers, and using data to assess financial opportunities under the model.

We acknowledge commenters' concern that some hospitals not in a selected MSA may desire to participate in the CJR model. We also note that CMS will continue to test voluntary bundled payment models, including those already undergoing testing through the BPCI initiative, which offered several open periods over the past few years where interested hospitals and other organizations could join. We expect that many providers will continue to engage in initiatives such as BPCI, and may also participate in other emerging models in the coming years. The coexistence of voluntary initiatives such as BPCI alongside new models in which providers are required to participate will provide CMS, providers, and beneficiaries with multiple opportunities to benefit from various care redesign and payment reform initiatives. We will also continue

to explore alternative approaches that may also prove effective in improving care for beneficiaries while reducing spending.

We disagree that requiring participation in the CJR model could create confusion and competing incentives for hospitals already participating in voluntary initiatives. We note that simultaneous testing of multiple bundled payment models is appropriate in many situations, depending on the care targeted under each model. Section III.C.7. of this final rule lays out our policies for accounting for overlap between models and contains discussion of the potential synergies and improved care coordination we expect will ensue through allowing for hospitals and beneficiaries to be engaged in more than one initiative simultaneously.

We appreciate that not all hospitals will have contractual arrangements with providers and suppliers furnishing services to beneficiaries during LEJR episodes. However, this final rule lays out the various financial arrangements that will be permitted under the CJR model, to allow hospitals the opportunity to engage with other providers and suppliers and to form clinical and financial partnerships. Section III.C.10. of this final rule details the requirements for these financial arrangements. Although hospitals will not be required to form financial relationships with other providers and suppliers, we expect many will do so in order to help align the clinical and financial incentives of key providers and suppliers caring for CJR model beneficiaries.

Finally, we do not see how participation in the CJR model, in and of itself, would lead to beneficiary harm and that if beneficiary harm were to occur, that CMS would be responsible. First, and most importantly, we note that under the model, providers and suppliers are still required to provide all medically necessary services, and beneficiaries are entitled to all benefits that they would receive in the absence of the model. Second, we note that we have employed many payment systems, such as IPPS, and payment models, such as BPCI and ACOs, that include similar economic incentives to promote efficiency, and we have not determined that beneficiaries have been harmed by those systems and models. Third, we note that CMS has numerous tools and monitoring plans which are both specific to this model and common to all FFS Medicare. These include audits, monitoring of utilization and outcomes within the model, and the availability of Quality Improvement Organization (QIOs) and 1–800–MEDICARE for reporting beneficiary concerns, among other protections. The CJR model includes monitoring to ensure beneficiary access, choice, and quality of care is maintained under the model. We refer readers to section III.F. of this final rule for discussion of beneficiary protections and monitoring under the CJR model. The model pricing structure, discussed in III.C. of this final rule, also includes features to protect against such potential harm, such as responsibility for post-episode spending increases, stop-gain policies that set a maximum threshold a hospital can earn for savings achieved during episodes, and other policies as detailed in that section. In summary, we note that this payment model does not constrain the practice of medicine and we do not expect clinical decisions to be made on the basis of the payment amount.

*Comment:* Several commenters stated that all states selected to participate in the proposed HHVBP should be exempted from having to participate in the CJR model. Commenters stated that forcing HHAs to participate in two mandatory models simultaneously is harsh and punitive and would likely skew the results of both models in areas of overlap.

*Response:* Only participant hospitals under the CJR model are financially responsible to CMS for the episode of care. HHAs will continue to be paid the FFS amount that they would otherwise receive for beneficiaries included in the CJR model. Therefore, there is no reason to exempt hospitals located in MSAs selected for participation in CJR that are also located in states selected for participation in the HHVBP model.

*Comment:* Many commenters expressed concern with the interaction between BPCI and the proposed joint replacement model due to instances where LEJR episodes excluded from CJR due to BPCI would cause a low volume issue for certain hospitals. Other commenters stated that the proposed CJR model penalizes providers that are voluntarily participating in the BPCI initiative and suggested that CMS allow hospitals in selected MSAs to be allowed to choose between participation in BPCI and the joint replacement model.

*Response:* Because there are LEJR episodes currently being tested in BPCI Models 1, 2, 3 and 4, we noted in the proposed rule that we believed that participation in CJR should not be required if it would disrupt testing of LEJR episodes already underway in BPCI models. Therefore, we proposed that IPPS hospitals located in an area selected for the model that are active Model 1 BPCI participant hospitals as of July 1, 2015, or episode initiators for LEJR episodes in the risk-bearing phase of Model 2 or 4 of BPCI as of July 1, 2015, would be excluded from participating in CJR during the time that their qualifying episodes are included in one of the BPCI models. We clarify that we will utilize current information on BPCI participation to determine whether a given hospital is included in CJR. For example, if a hospital elected to participate in the LEJR episode under BPCI Model 2 in September 2015, that hospital would not be included in CJR during the time that their qualifying episodes are included in BPCI. Likewise, we proposed that if the participant hospital is not an episode initiator for LEJR episodes under BPCI Model 2, then LEJR episodes initiated by other providers or suppliers under BPCI Model 2 or 3 (where the surgery takes place at the participant hospital) would be excluded from CJR. Otherwise qualifying LEJR episodes (that is, those that are not part of a Model 3 BPCI LEJR episode or a Model 2 PGP-initiated LEJR episode) at the participant hospital would be included in CJR. We are testing a model where participation is not voluntary; therefore, it would not be appropriate for hospitals in selected MSAs to be allowed to choose between participation in BPCI and the joint replacement model. If hospitals were allowed to voluntarily participate in the CJR model, this would introduce selection bias and hamper CMS' ability to analyze how such a payment model potentially would work on a national scale. In addition, a hospital interested in participating in a voluntary model had the opportunity under BPCI. In response to concerns regarding the interaction between BPCI and CJR and potential for too few LEJR episodes at a given hospital to remain under the CJR model, low volume concerns are discussed and addressed in section III.A.4.b of this final rule.

*Comment:* Some commenters requested CMS to allow hospitals participating in ACOs that achieved shared savings in recent performance periods, Shared Savings Program ACOs (Track 2 and Track 3), and full-risk ACOs (such as Next Generation ACO), to opt-out of participation in the CJR model.

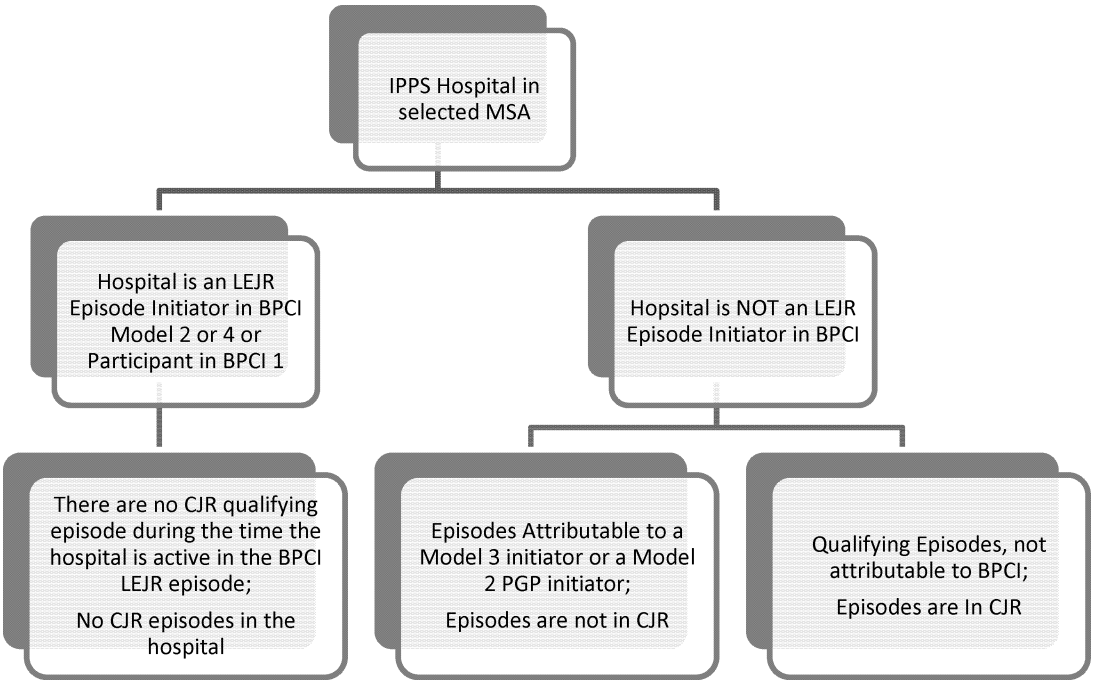
*Response:* As we previously noted and in the proposed rule, many hospitals have recently heightened their focus on aligning their efforts with those of community providers to provide an improved continuum of care due to the incentives under other CMS models and programs. Therefore, hospitals that are already involved in ACO initiatives and

the HRRP have already established a base for augmenting these efforts under the CJR model (80 FR 41205). Therefore, we see no compelling reason why hospitals participating in ACO initiatives and other efforts cannot be participant hospitals in the CJR model. However, adjustments to account for overlaps with other innovation center models and CMS programs are discussed in section III.C.7. of this final rule.

*Comment:* A commenter stated that a CMS Certification Number (CCN) can include multiple hospitals. The commenter inquired, if at least one hospital under the CCN is in a selected MSA, would the entire CCN be required to participate in the CJR model. The commenter also requested if some of the hospitals in the CCN are not eligible for the CJR program, would they be required to participate because they are under the same CCN.

*Response:* The proposed approach indicated that CMS would base selection on the physical location of the hospital. The manner in which CMS tracks and identifies hospitals is through the CCN. In keeping with this approach, the CJR model will administer model-related activities at the CCN level including the determination of physical location. The physical location associated with the CCN at the time of the model start will be used to determine whether that CCN is located in a selected MSA. For hospitals that share a CCN across various locations, all hospitals under that CCN would be required to participate in the CJR model if the physical address associated with the CCN is in the MSA, unless otherwise excluded. Similarly, all hospitals under the same CCN, even if some are physically located in the MSA selected for participation, would not participate in in the CJR model if the physical address associated with the CCN is not in the MSA. Our analysis of the hospitals in the selected MSAs indicates that this phenomenon is not present in the selected areas.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to designate IPPS hospitals as the episode initiators. The initiation of an episode is described in § 510.100. We are also finalizing our proposal to require IPPS hospitals physically located in an area selected for participation in the CJR model, according to the address associated with the CCN, to participate in the model and bear the financial responsibility for LEJR episodes of care under the CJR model. Finally, we are finalizing our proposal that hospitals selected for the model that are active Model 1 BPCI participant hospitals as of July 1, 2015, or episode initiators for LEJR episodes in the risk-bearing phase of Model 2 or 4 of BPCI as of October 1, 2015, are excluded from participating in CJR during the time that their qualifying episodes are included in one of the BPCI models. However, LEJR episodes initiated by other providers or suppliers under BPCI Model 2 or 3 (where the surgery takes place at the participant hospital) are excluded from CJR. Otherwise qualifying LEJR episodes (that is, those that are not part of a Model 3 BPCI LEJR episode or a Model 2 physician group practice-initiated LEJR episode) at the participant hospital are included in CJR. The definition of a ''participant hospital'' and ''CJR-regional hospital'' will be codified in § 510.2, exclusions to episodes being tested due to BPCI overlap will be codified in § 510.100(b). The following chart illustrates the inclusion of episodes in CJR relative to BPCI.




4. Geographic Unit of Selection and Exclusion of Selected Hospitals

In determining which hospitals to include in the CJR model, we considered whether the model should be limited to hospitals where a high volume of LEJRs are performed, which would result in a more narrow test on the effects of an episode-based payment, or whether to include all hospitals in particular geographic areas, which would result in testing the effects of an episode-based payment approach more broadly across an accountable care community seeking to coordinate care longitudinally across settings. Selecting certain hospitals where a high volume of LEJRs are performed may allow for fewer hospitals to be selected as model participants, but still result in a sufficient number of CJR episodes to

evaluate the success of the model. However, there would be more potential for behavioral changes that could include patient shifting and steering between hospitals in a given geographic area that could impact the test. Additionally, this approach would provide less information on testing episode payments for LEJR procedures across a wide variety of hospitals with different characteristics. Selecting geographic areas and including all IPPS hospitals in those areas not otherwise excluded due to BPCI overlap as previously described and in section III.C.7. of the proposed rule as model participants would help to minimize the risk of participant hospitals shifting higher cost cases out of the CJR model. Moreover, in selecting geographic areas we could choose certain characteristics, stratify geographic areas according to these characteristics, and randomly select geographic areas from within each stratum. Such a stratified random sampling method based on geographic area would allow us to observe the experiences of hospitals with various characteristics, such as variations in size, profit status, and episode utilization patterns, and examine whether these characteristics impact the effect of the model on patient outcomes and Medicare expenditures within episodes of care. Stratification would also substantially reduce the extent to which the selected hospitals will differ from non-selected hospitals on the characteristics used for stratification, which would improve the statistical power of the subsequent model evaluation, improving our ability to reach conclusions about the model's effects on episode costs and the quality of patient care. Therefore, given the authority in section 1115A(a)(5) of the Act, which allows the Secretary to elect to limit testing of a model to certain geographic areas, we proposed to use a stratified random sampling method to select geographic areas and require all hospitals paid under the IPPS in those areas to participate in the CJR model and be financially responsible for the cost of the episode, with certain exceptions as previously discussed and in sections III.B.3 and III.C.7. of the proposed rule.

a. Overview and Options for Geographic Area Selection

In determining the geographic unit for the geographic area selection for this model, we considered using a stratified random sampling methodology to select—(1) Certain counties based on their Core-Based Statistical Area (CBSA) status, (2) certain zip codes based on their Hospital Referral Regions (HRR) status; or (3) certain states. We address each geographic unit in turn.

We considered selecting certain counties based on their CBSA status. A CBSA is a core area containing a substantial population nucleus, together with adjacent communities having a high degree of economic and social integration within that core. Counties are designated as part of a CBSA when the county or counties or equivalent entities are associated with at least one core (urbanized area or urban cluster) of at least 10,000 in population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties associated with the core. There are 929 CBSAs currently used for geographic wage adjustment purposes across Medicare payment systems.[4] The 929 CBSAs include 388 MSAs, which have an urban core population of at least 50,000, and the 541 Micropolitan Statistical Areas (μSA), which have an urban core population of at least 10,000 but less than 50,000. CBSAs may be further combined into a Combined Statistical Area (CSA) which consists of two or more adjacent CBSAs (MSAs or μSAs or both) with substantial employment interchange. Counties not classified as a CBSA are typically categorized and examined at a state level.

The choice of a geographical unit based on CBSA status could mean selection of a CBSA, an MSA, or a CSA. We proposed basing the selection on an MSA, which we will discuss later in this section.

We proposed that counties not in an MSA would not be subject to the selection process. These counties not subject to selection would include the μSA counties and the counties without a core urban area of at least 10,000. These areas are largely rural areas and have a limited number of qualifying LEJR cases. Relatively few of these areas would be able to qualify for inclusion based on the minimum number of LEJR episodes in year requirement discussed later in this section.

We considered, but ultimately decided against, using CSA designation instead of MSAs as a potential unit of selection. Under this scenario, we would look at how OMB classifies counties. We would first assess whether a county has been identified as belonging to a CSA, a unit which consists of adjacent MSAs or μSAs or both. If the county was not in a CSA, we would determine if it was in an MSA that is not part of a larger CSA. Counties not associated with a CSA or an MSA would be unclassified and excluded from selection. These unclassified areas would include the counties in a state that were either not a CBSA (no core area of at least 10,000) or associated with a μSA (core area of between 10,000 and 50,000) but unaffiliated with a CSA.

Whether to select on the basis of CSA/MSAs or just on MSAs was influenced by a number of factors. We considered the following factors:

- CSAs, by definition, have a significantly lower degree of interchange between component parts than the interchange experienced within an MSA. Thus, we did not believe that using CSAs would be necessary in order to capture referral patterns. A case study examination of the geographic areas included in CSAs with respect to the health care markets of those areas and their respective parts helped to validate our conclusion.
- We assessed the anticipated degree to which LEJR patients would be willing to travel for their initial hospitalization.
- We assessed the extent to which surgeons are expected to have admitting privileges in multiple hospitals located in different MSAs.
- We considered the degree to which we desire to include hospitals within μSAs that are part of a larger CSA.

After examining these factors, we concluded that that the anticipated risk for patient shifting and steering between MSAs within a CSA was not severe enough to warrant selecting CSAs given CMS' preference for smaller geographic units. However, because MSAs are units with significant levels of social and commercial exchange and due to the mobility of patients and providers within MSAs, we believed that selecting complete MSAs is preferable to selecting metropolitan divisions of MSAs for inclusion in the CJR model. We use the metropolitan divisions to set wage indices for its prospective payment systems (PPSs). Of the 388 MSAs, there are 11 MSAs that contain multiple metropolitan divisions. For example, the Boston-Cambridge-Newton, MA–NH MSA is divided into the following metropolitan divisions:

- Boston, MA.
- Cambridge-Newton-Framingham, MA.
- Rockingham County-Strafford County, NH.

[4] As stated in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27552) and final rule (78 FR 50586), on February 28, 2013, OMB issued OMB Bulletin No.13–01, which established revised delineations for MSAs, μSA s, and CSAs, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.*

The Seattle-Tacoma-Bellevue, WA MSA is divided into the following metropolitan divisions:

- Seattle-Bellevue-Everett, WA.
- Tacoma-Lakewood, WA.

We proposed selecting entire MSAs rather than sub-divisions within an MSA.

We next considered selecting HRRs. HRRs represent regional health care markets for tertiary medical care. There are 306 HRRs with at least one city where both major cardiovascular surgical procedures and neurosurgery are performed. HRRs are defined by determining where the majority of patients were referred for major cardiovascular surgical procedures and for neurosurgery.[5] Compared to MSAs, HRRs are classified based on where the majority of beneficiaries within a zip code receive their hospital services for selected tertiary types of care. The resulting HRRs represent the degree to which people travel for tertiary care that generally requires the services of a major referral center and not the size of the referral network for more routine services, such as knee and hip arthroplasty procedures. In addition, because HRRs are defined based on referrals for cardiovascular surgical procedures and neurosurgery, they may not reflect referrals for orthopedic procedures. Therefore, we believed that MSAs as a geographic unit are preferable over HRRs for this model.

We also considered selecting states for the CJR model. However, we concluded that MSAs as a geographic unit are preferable over states for the CJR model. As stated in section III.A.4.b. of the proposed rule, we anticipate that hospitals that would otherwise be required to participate in the CJR model would be excluded from the model because their relevant LEJR episodes are already being tested in BPCI. If we were to select states as the geographic unit, there is a potential that an entire state would need to be excluded because a large proportion of hospitals in that state are episode initiators of LEJR episodes in BPCI. In contrast, if we excluded a specific MSA due to BPCI participation, as discussed in the next section, we could still select another MSA within that same state. Likewise, if we chose states as the geographic unit, we would automatically include hospitals in all rural areas within the state selected. If MSAs are selected for the geographic unit, we anticipate that fewer small rural hospitals would be included in the model. Using a unit of selection smaller than a state would allow for a more deliberate choice about the extent of inclusion of rural or small population areas. Selecting states rather than MSAs would also greatly reduce the number of independent geographic areas subject to selection under the model, which would decrease the statistical power of the model evaluation. Finally, MSAs straddle state lines where providers and Medicare beneficiaries can easily cross these boundaries for health care. Choosing states as the geographic unit would potentially divide a hospital market and set up a greater potential for patient shifting and steering to different hospitals under the model. The decision that the MSA-level analysis was more analytically appropriate was based on the specifics of this model and is not meant to imply that other levels of selection would not be appropriate in a different model such as the proposed HHVBP model.

For the reasons previously discussed, we proposed to require all IPPS hospitals to participate in the CJR model (with limited exceptions as previously discussed in section III.A.2. of the proposed rule) if located in an MSA selected through a stratified random sampling methodology (outlined in section III.A.3.b. of the proposed rule) to test and evaluate the effects of an episode-based payment approach for an LEJR episodes. We proposed to determine that a hospital is located in an area selected if the hospital is physically located within the boundary of any of the counties in that MSA where the counties are determined by the definition of the MSA as of the date the selection is made. In response to comments, we are clarifying that we will determine physical location using the address associated with the CCN of the hospital. Although MSAs are revised periodically, with additional counties added or removed from certain MSAs, we proposed to maintain the same cohort of selected hospitals throughout the 5 performance years of the model with limited exceptions as described later in this section. Thus, we proposed that, if after the start of the model, new counties are added to one of the selected MSAs or counties are removed from one of the selected MSAs, those re-assigned counties would retain the same CJR status they had at the beginning of the initiative. We believed that this approach will best maintain the consistency of the participants in the model, which is crucial for our ability to evaluate the results of the model. We retain the possibility of adding a hospital that is opened or incorporated within one of the selected counties after the selection is made and during the period of performance. (See section III.C.4. of the proposed rule for discussion of how target prices will be determined for such hospitals.) Hospitals in selected counties that do not have any LEJR cases that qualify for CJR, due to their participation in the BPCI initiative as a hospital initiator in an LEJR episode, will become subject to CJR at the time their participation in BPCI ends and their episodes become eligible for CJR. Although we considered including hospitals in a given MSA based on whether the hospitals were classified into the MSA for IPPS wage index purposes, this process would be more complicated, and we could not find any compelling reasons favoring this approach. For example, we assign hospitals to metro divisions of MSAs when those divisions exist. See our previous discussion of this issue. In addition, there is the IPPS process of geographic reclassification by which a hospital's wage index value or standardized payment amount is based on a county other than the one where the hospital is located. For the purpose of this model, it is simpler and more straightforward to use the hospital's physical location as the basis of assignment to a geographic unit. This decision would have no impact on a hospital's payment under the IPPS. We sought comment on our proposal to include participant hospitals for the CJR model based on the physical location of the hospital in one of the counties included in a selected MSA.

The following is a summary of the comments received and our responses.

*Comment:* Commenters generally supported MSAs as the unit of geographic selection. However, several had concerns regarding the particular circumstances of their MSAs. Some commenters stated that MSAs were too large and preferred the use of metropolitan regions for large urban areas such as New York City, while others expressed concern with the inclusion of rural portions of the MSA counties. Commenters addressing the rural providers within the selected MSAs questioned whether the inclusion of rural hospitals in the model was deliberate or whether CMS believed hospitals in rural areas should not be included in the CJR model. Other commenters expressed concern that MSAs were a smaller than ideal unit of selection and that selecting MSAs for the model would encourage practices such as funneling patients to hospitals outside a selected MSA for surgery in order to avoid inclusion in the model. Conversely, a commenter asserted that

[5] The Dartmouth Atlas of Healthcare, *http://www.dartmouthatlas.org/data/region/*. Accessed on April 9, 2015.

participation in the model would result in a competitive advantage for hospitals in a selected MSA through the use of gainsharing to recruit physicians to move referrals into a selected market. Some commenters were also concerned about patient shifting in or out of a selected MSA in areas where the MSA was part of a larger CSA, such as in the Atlanta CSA in which some, but not all, component MSAs were selected for participation in the CJR model.

*Response:* We first address the issue of the inclusion of the entirety of an MSA as the unit of selection rather than just the core urban area. This was a deliberate choice reflecting the fact that we seek to examine the performance of hospitals under CJR that could be considered rural, low volume, or outside the urban core. Inclusion of such hospitals in the model will give us insight on how the model functions in these areas and increase the potential generalizability of the model. The proposed rule proposed additional protections to selected classes of hospitals such as SCHs, Medicare-Dependent Hospitals (MDHs), and RCHs because we wanted to further protect these federally-recognized categories of vulnerable hospitals while including them in the model.

We chose MSAs as the unit of selection to balance the following considerations: The scope for shifting patients in or out of selected areas, our ability to observe the impact of the model in a variety of circumstances, and our preference to not use a geographic unit larger than strictly necessary to evaluate the model. We acknowledge that there are inevitably tradeoffs among these criteria. With respect to the choice of CSA versus MSA, a far greater number of commenters were concerned with the inclusion of rural providers than were concerned with their or their competitor's markets crossing the borders of MSAs within a CSA. By definition, CSAs have a lesser degree of the employment interchange than an MSA and basing the geographic unit of selection on a CSA would entail the possibility of selecting μSAs within CSAs. On balance, we believe it is appropriate to limit the extent of rural participation in CJR by confining it to rural areas within MSAs. We are sympathetic to concerns related to the experience of hospitals that are located near the borders between MSAs, but believed that those concerns did not outweigh these other considerations. In contrast, the density of populations and providers at the borders of these markets was one of the reasons that we decided to not proceed with allowing selection to be done based on metropolitan divisions for those 11 MSAs that were so sub-divided. Metropolitan divisions are very likely to have hospitals whose referral markets straddle divisions and their use as a unit would have had been problematic. After weighing the comments we continue to believe that MSAs are the most appropriate compromise position for the choice of geographic unit of selection.

Finally, we note that separate commenters stated that a hospital in a CJR selected county could be either at both a competitive advantage (for example, by providing an opportunity to attract physicians through gainsharing), or a competitive disadvantage (for example, by causing physicians to shift patients to nearby hospitals). We believe that both phenomena may occur and that the ability of a hospital to use the opportunities presented to it under the CJR model to strengthen its relationship with other providers and potentially achieve savings will vary by the hospital's specific circumstances and capabilities. We do not see a strong argument for why these types of effects necessitate a change to the geographic unit used for this model.

*Comment:* Some commenters contended that the CJR model has inadequate participation by small and rural providers due to the elimination of non-CBSA and μSAs from the possibility of selection for this model. The commenters wrote that CMS should include more rural providers in order to foster a model that is not overly tailored to large providers and urban areas. A commenter stated that inclusion in the model would result in rural providers being more prepared to adapt to future payment and delivery reforms. Another stated that it was important to include more small volume hospitals, and urged CMS to reconsider the implications of this exclusion and to broaden the definition of geographic areas.

*Response:* We appreciate commenters' input on how to incorporate rural providers in the CJR model and acknowledge commenters' concerns related to the ability of small and rural providers to effectively participate and succeed in the model. Our proposed approach to including low-volume and non-urban providers within the selected MSAs but removing from the possibility of selection counties that are not in an MSA or in an MSA with less than 400 qualifying LEJR cases is an appropriate strategy that allows for inclusion of rural providers in the model, while not oversampling such providers.

Comments related to requests for exclusion of particular hospitals are addressed in the next section, MSA Selection Methodology. Financial protections for hospitals are addressed later in section III.C.8. of this final rule.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal, without modification, to utilize MSAs as the unit of selection for the model.

b. MSA Selection Methodology

We proposed to select the MSAs to include in the CJR model by stratifying all of the MSAs nationwide according to certain characteristics.

(1) Exclusion of Certain MSAs

Prior to assigning an MSA to a selection stratum, we examined whether the MSA met specific proposed exclusion criteria. MSAs were evaluated sequentially using the following 4 exclusion criteria: First, MSAs in which fewer than 400 LEJR episodes (determined as discussed in section III.B.2. of this final rule) occurred from July 1, 2013 through June 30, 2014 were removed from possible selection. The use of the 400 LEJR cases in a year was based on a simple one-sided power calculation to assess the number of episodes that would be needed to detect a 5 percent reduction in episode expenditures. Cases in hospitals paid under either the critical access hospital (CAH) methodology or the Maryland All-Payer Model are not included in the count of eligible episodes. This criterion removed 156 MSAs from possible selection.

Second, MSAs were removed from possible selection if there were fewer than 400 non-BPCI LEJR episodes in the MSA in the reference year. For the purposes of this exclusion, the number of BPCI episodes was estimated as the number of potentially eligible cases during the reference year that occurred in acute care hospitals participating in BPCI Model 1, or in phase 2 of BPCI Models 2 or 4 as of July 1, 2015 and the number of LEJRs in the reference year associated with these hospitals was examined. This criterion removed an additional 24 MSAs from potential selection.

Third, MSAs were also excluded from possible selection if the MSA was dominated by BPCI Models 1, 2, 3, or 4 episodes to such a degree that it would impair the ability of participants in either the CJR model or the BPCI models to succeed in the objectives of the initiative or impair the ability to set accurate and fair prices. We anticipate that some degree of overlap in the two models will be mutually helpful for both models. There are two steps to this exclusion. First, we looked at the number of LEJR episodes at BPCI Model 1, 2 or 4 initiating hospitals and second,

the number of LEJR episodes among BPCI Model 3 SNF and Home Health Agency (HHA) episode initiators. First, we excluded MSAs if more than 50 percent of otherwise qualifying proposed CJR episodes were in Phase 2 of BPCI Model 2 or 4 with hospital initiators. Second, we excluded MSAs if either SNF or HHA BPCI Model 3 initiating providers accounted for more than 50 percent of LEJR referrals to that provider type. As a result of this third criterion, 4 additional MSAs were removed from possible selection. No MSAs were excluded based on SNF or HHA participation in Model 3.

Finally, MSAs were removed if, after applying the previous three criteria they remained eligible for selection, but more than 50 percent of estimated eligible episodes during the reference year were not paid under the IPPS system. The purpose of this rule was to assess the appropriateness of MSAs that contained both Maryland and non-Maryland counties. No MSAs were eliminated on the basis of this rule. Please refer to the appendix for this final rule for the status of each MSA based on these exclusion criteria, available at *http://innovation.cms.gov/initiatives/cjr/.* After applying these four exclusions, 196 MSAs remained to be stratified for purposes of our proposed selection methodology.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters requested that we exclude additional MSAs from the selection process. Commenters supported our exclusion of MSAs with less than a minimum number of eligible LEJR episodes and a high rate of BPCI LEJR penetration, but were concerned that the list of BPCI participating providers used in making the exclusion determination did not reflect providers entering BPCI as of October 1, 2015. Such commenters recommended that CMS recalculate BPCI participation in LEJR episodes in each MSA based on both hospital- and physician-led participants and adjust the MSA selection accordingly. Commenters also suggested adding additional selection criteria based on the overall percent of LEJR episodes associated with a BPCI episode, the percent of LEJR episodes associated with a PGP initiated BPCI episode, and the percent of LEJR episodes associated with an ACO.

*Response:* In response to the comments, we re-examined the exclusion rules based on an updated list of providers participating in the BPCI initiative for LEJR episodes. We also examined the potential impact on selection of MSAs that incorporating an updated list of BPCI participants would have. For the purposes of the re-examination of exclusion rule 2, which eliminates MSAs with less than 400 CJR eligible, non-BPCI episodes, we estimated the BPCI LEJR episode count as the number of potentially eligible cases during the reference year that (1) occurred in an acute care hospital participating in BPCI Model 1 that would still be active as of April 1, 2016; (2) occurred in an acute care hospital in a Phase 2 LEJR episode for BPCI Models 2 or 4 as of October 1, 2015; or (3) were associated with an operating or admitting physician on the hospital claim assigned to a PGP with an LEJR episode in Phase 2 of BPCI Model 2 as of October 1, 2015. October 1, 2015 is the final quarter for which participants in Phase 1 of BPCI could transition any episode into Phase 2. This represents a change to the exclusion rule articulated in the proposed rule, in that it updates the list of BPCI participants and also takes into account episodes associated with Model 2 PGP episode initiators. As we did for exclusion rule 2, we used the October 2015 list of BPCI participants to reassess exclusion rule 3. Rule 3 removes an MSA if more than 50 percent of patients were treated in a BPCI initiating hospital or if more than 50 percent of LEJR patients treated in a PAC setting of that type were treated in a BPCI initiating HHA or SNF.

After we made the previously stated changes, some MSAs previously eligible for selection would now be considered excluded. Additionally, two of the MSAs previously excluded would now be eligible for selection due to hospitals withdrawing from BPCI and the MSAs now having more than 400 eligible cases. Eight MSAs that were selected in the proposed rule would be classified as excluded on the basis of these updated exclusion rules.

We considered a variety of alternative approaches to address the changes in the eligibility of MSAs. First, we considered proceeding with the list of 75 MSAs as initially selected and using the exclusion rules as initially proposed. Second, we considered removing the 8 selected MSAs that would now be excluded on the basis of the updated BPCI participation numbers. Third, we considered replacing the 8 MSAs by randomly selecting new MSAs from the remaining MSAs in the relevant strata. However, we believed that it would preferable, although not required, to give the selected MSAs a consistent period of time between selection and the start of the model. Fourth, we contemplated creating a revised list of eligible MSAs and randomly selecting a new group of 75 MSAs. Given the concern of many commenters about the start date of the model, we were reluctant to create a completely new list of selected MSAs. We believe that making a new selection would be regarded unfavorably by impacted MSAs and hospitals and should be avoided if possible. In order to be responsive to concerns regarding the growth of BPCI after the publication of the proposed rule and the increase in PGP participation in BPCI, we are proceeding with the second option.

The function of the stratification approach was to ensure that our selection of MSAs covered a range of efficiency levels and population sizes and allowed us to target our sampling percentages so as to oversample in the less efficient areas. Regarding the selected MSAs now eliminated, they are distributed fairly evenly throughout the distribution of average episode payments. From the least expensive to the most expensive quartiles, the number selected and now eliminated are, in order, 2/15 (13 percent), 2/19 (11 percent), 3/30 (15 percent), and 1/22 (5 percent). We also believe that the removal of these 8 MSAs from the model will not preclude us from undertaking a rigorous statistical evaluation of the model.

Given the aforementioned information, we believe that the relatively minor reduction in statistical power due to not re-selecting MSAs is outweighed by the desire to give affected participant hospitals equal time to prepare for the model. We are removing the 8 MSAs as noted in Table 1.

TABLE 1—MSAS THAT WERE PREVIOUSLY SELECTED THAT ARE NO LONGER INCLUDED IN CJR

| CBSA title | Revised exclusion rule 2 status | Revised exclusion rule 3 status |
|---|---|---|
| Colorado Springs, CO | Fail | Pass. |
| Evansville, IN–KY | Fail | Pass. |
| Fort Collins, CO | Fail | Pass. |
| Las Vegas-Henderson–Paradise, NV | Fail | Fail. |

TABLE 1—MSAs THAT WERE PREVIOUSLY SELECTED THAT ARE NO LONGER INCLUDED IN CJR—Continued

| CBSA title | Revised exclusion rule 2 status | Revised exclusion rule 3 status |
|---|---|---|
| Medford, OR | Fail | Pass. |
| Richmond, VA | Fail | Pass. |
| Rockford, IL | Fail | Pass. |
| Virginia Beach-Norfolk-Newport News, VA–NC | Pass | Fail. |

We next contemplated whether to apply additional MSA-level exclusion rules. We investigated a potential new rule whereby an MSA would be excluded based on the percent of the MSA's qualifying LEJR episodes associated with Phase 2 Model 2 PGP initiators. We did not believe that there was as strong of an argument for excluding MSAs on the basis of the percent of patients treated by a BPCI physician given that the hospital is the financially accountable entity in CJR. We examined two possible cut off points (>65 percent and >50 percent) to assess which MSAs would be eliminated if we were to exclude MSAs where a specific percent of an MSA's otherwise qualifying LEJR cases was attributable to a BPCI PGP. At 65 percent, no selected MSAs not otherwise excluded were impacted. 8 MSAs that were previously selected had more than 50 percent of their LEJRs performed by BPCI PGPs. Five of these 8 MSAs are already eliminated due to the revised exclusion rule 2. For markets with more than 400 non-BPCI cases but more than 50 percent BPCI PGP penetration, the number of the CJR eligible patients was between 556 and 1834 indicating that there was a sizable number of cases. Consequently, we did not find this new exclusion rule necessary.

*Comment:* Commenters requested modifications to the proposed exclusions of specific categories of hospitals within an MSA. While commenters stated a variety of concerns, many of them were related to the request that CMS exclude low volume hospitals from the model. Commenters made requests around specific categories of hospitals including Medicare Dependent Hospitals (MDHs), Sole Community Hospitals (SCHs), Rural Referral Centers (RRCs), hospitals that are reclassified as rural, hospitals perceived of as rural or outside of a core urban area, and larger hospitals with a low potential CJR LEJR volume due to the exclusion of their patients because their LEJR episodes were initiated by a PGP BPCI LEJR episode initiator.

Commenters provided a variety of rationales for why they believed it was undesirable or unfair to include low volume providers in the model. These reasons include, but are not limited to, observations that—

- Low-volume providers are less likely to be proficient at taking care of these patients in an efficient cost-effective manner and they will be less likely to achieve savings;
- Low-volume hospitals will be disproportionately impacted by outlier cases and will have less predictable cost and quality outcomes making it difficult for them to manage the model effectively. In addition, low volume providers are likely to see a greater proportion of hip fractures and non-planned procedures;
- Low-volume hospitals will have less control over and ability to impact the behavior of other providers. The pool of collaborating providers such as orthopedic surgeons in most rural communities may be limited and small hospitals may not have the market position to successfully influence others' behavior;
- Hospitals with a limited number of Medicare hip and knee procedures may not have sufficient incentive to invest the time and resources necessary to develop the infrastructure and partnerships required to effectively manage these episodes of care and may not find the opportunity to improve patient outcomes significant enough to engage referring physicians and PAC partners for redesign;
- Low volume providers may be more financially vulnerable and with fewer resources to design and carry out initiatives or make effective responses to the financial incentives in the model. A commenter noted concerns with hospital margins, and the possibility for the reductions in revenue as a result of the loss of volume or loss of margin under CJR could result in additional hospital closures.

Due to these concerns, commenters requested a variety of solutions including (1) the exclusion of hospitals based on a volume cut off variously defined by volume of eligible LEJR cases, LEJR cases within specific MS–DRGs and total hospital volume, (2) making the model voluntary for low volume providers, (3) extending the protections afforded to SCH, MDH and RRC to additional categories of hospitals including hospitals electing to be treated as rural under § 412.103, and (4) the provision of additional protections or payment adjustments beyond what was included in the proposed rule.

*Response:* We acknowledge the fact that hospitals, particularly low volume hospitals, are concerned and would like to increase their probability of receiving reconciliation payments under CJR while minimizing the possibility of reduction in revenue. We refer readers to the following sections of this final rule: Section III.C.8. for a discussion of hospital financial protections, III.C.4. for a discussion of how we will determine target prices for hospitals with low volume, and section III.C.4. for a discussion of target prices for hip fracture patients. We believe that the modification of the treatment of hip fractures in the payment methodology should allay many concerns of small and rural providers. This change may disproportionately impact them since emergency surgeries, such as hip fractures, have a higher probability of being performed in low volume settings.

As stated in relation to comments requesting that CJR operate as a voluntary model, the inclusion of low volume hospitals in the CJR model is consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure, care redesign experience, market position, and other considerations and circumstances. The design of the CJR model and the inclusion of low volume providers within the model reflects our interest in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those hospitals that may not otherwise participate in such a test. The inclusion of these providers allows CMS to better appreciate and understand how the model operates as a general payment approach and its impact on a wide range of hospitals. Many LEJR surgeries are performed in low volume settings, thus, the impact of the CJR model on low volume hospitals is of great interest to the evaluation of this initiative.

We acknowledge that providers with low volumes of cases may not find it in their financial interests to make

systematic care redesigns or engage in an active way with the CJR model. We expect that low volume providers may decide that their resources are better targeted to other efforts because they do not find the financial incentive present in the CJR sufficiently strong to cause them to shift their practice patterns. We acknowledge that low volume hospitals may achieve less savings because they did not or could not make the necessary changes to the treatment of their qualifying beneficiary population. We believe this choice is similar in nature to that made as hospitals decide their overall business strategies and where to focus their attentions.

*Comment:* Many commenters requested that CMS exclude hospitals where more than 50 percent of the eligible LEJRs performed at a hospital would be attributed to a PGP initiated BPCI episode and would thus not be in CJR. The majority of these commenters were concerned about low volumes of patients, which is addressed in the previous comment and response. Some were concerned about the operational complexity of identifying, tracking, and managing patients treated in CJR versus BPCI.

*Response:* We will not exclude IPPS hospitals in selected MSAs other than as already specified or allow IPPS hospitals to opt out of participation in CJR. As previously noted in the discussion on low volume hospitals, we consider the inclusion of low volume providers a core feature of the model that will aid us in understanding the impact of a variety of providers in various circumstances. Similarly, we do not believe it is necessary or appropriate to exclude hospitals on the basis of some of the surgeons in their hospitals being associated with a BPCI PGP. Like with more traditional low volume providers, the extent to which a hospital alters its behavior in response to the CJR model will likely be the result of a variety of factors including but not limited to the anticipated number of cases. It should be noted that the revised exclusion rule that resulted in the elimination of 8 MSAs was based on failing to meet a minimum MSA number of LEJRs and not based on either the number of LEJRs at a particular hospital or the portion of PGPs at any level of analysis. If an IPPS hospital in a selected area has some of their LEJR cases qualify as CJR episodes and some that do not due to BPCI participation, Medicare Advantage status or any other reason, the fact that CJR cases are not their full caseload will not be considered a reason for exclusion of the hospital.

With respect to challenges that hospitals may experience related to identifying eligible patients and following them over the course of their episodes, we acknowledge that concern. However, we consider the improved tracking and communication with other providers and suppliers that is likely to occur as a result of hospital efforts in CJR to be a benefit of the model that will improve the coordination of patient care and possibly improve patient outcomes.

*Comment:* Two commenters raised the issue of hospital systems spanning more than one MSA. They requested that CMS either allow all of the hospitals in the system to be included in CJR or allow all of the hospitals to be excluded. Commenters stated that the additional administrative burden associated with two concurrent Medicare payment methodologies would be unduly burdensome. Additionally, commenters stated that CMS should develop criteria under which all providers in health systems with a significant number of BPCI participants would be excluded from the CJR model due to operational challenges to managing the BPCI and CJR models simultaneously within a health care system.

*Response:* With respect to the request that all members within a health system be allowed to have all of their hospitals participate in BPCI because operating under two systems is too onerous, if a health system made the choice to enter some but not all of their locations into BPCI, they have already made the business decision to operate partly under one incentive structure and partly under another. We do not believe that the existence of CJR model as proposed should change the timelines for transitioning to Phase 2 of BPCI. We will not exclude hospitals from the model on the basis that some of the hospitals in its health system are participating in BPCI or some of the hospitals in its health system have CCNs with addresses located in a non-selected MSA.

The CJR model will require hospitals within selected geographic areas to participate (unless otherwise excluded as set forth in this final rule). The inclusion of additional voluntarily participating hospitals outside of these selected areas would constitute a major change to the model that was not considered in the proposed rule. Providers who wished to participate in a voluntary episode model had the opportunity under the BPCI initiative.

*Final Decision:* After consideration of the public comments we received, we are modifying the MSA exclusion rules used in determining which MSAs are eligible for selection. The following is a description of the MSA exclusion criteria used in this final rule:

In determining if an MSA was eligible for selection, we first examined whether the MSA met any of the four exclusion criteria as formulated in the proposed rule. This process resulted in a pool of 196 MSA from which we then selected 75 for inclusion in CJR via stratified random selection.

In this final rule, we revised the exclusion rules as defined later in this section, with the purpose of assessing whether any of the 75 selected MSAs would be considered not eligible for selection based on applying the new criteria.

Specifically, the second exclusion rule, which eliminates MSAs with fewer than 400 non-BPCI CJR eligible cases, is modified with the following additions (1) the determination of the count of patients associated with a BPCI Phase 2 initiating hospital is based on the participation in BPCI as of October 1, 2015 rather than July 1, 2015 and (2) the count of BPCI episodes to be removed from the count of eligible episodes takes into consideration patients who would have been attributed to a BPCI Model 2 initiating PGP in Phase 2 for an LEJR episode as of October 1, 2015. The third exclusion rule, wherein MSAs were excluded based on the percent of the MSA's LEJR population associated with either a BPCI hospital, SNF or HHA in an MSA, was changed to be based on episodes associated with participation in BPCI as of October 1, 2015 rather than July 1, 2015.

As a result of updating the list of BPCI participants to those entering the model in October 2015 and including Phase 2 PGPs in the calculation of the number of cases in the MSA, 8 MSAs out of the 75 MSAs that were previously selected are now deemed not eligible for selection and are consequently no longer required to participate in CJR. These previously selected and now excluded MSAs are shown in Table 1. The remaining 67 MSAs selected in the proposed rule will be required to participate in CJR.

*(2) Selection Strata*

Numerous variables were considered as potential strata for classifying MSAs included in the model. However, our proposal was intended to give priority to transparency and understandability of the strata. We proposed creating selection strata based on the following two dimensions: MSA average wage-adjusted historic LEJR episode payments and MSA population size.

(a) MSA Average Wage-Adjusted Historic LEJR Episode Payments

We were interested in being able to classify and divide MSAs according to their typical patterns of care associated with LEJR episodes. As a straightforward measure of LEJR patterns of care, we selected the mean MSA episode payment, as defined in the proposed rule. MSAs vary in their average episode payments. The average episode payments in an area may vary for a variety of reasons including—(1) In response to the MS–DRG case mix and thus the presence of complicating conditions; (2) readmission rates; (3) practice patterns associated with type of PAC provider(s) treating beneficiaries; (4) variations of payments within those PAC providers, and (5) the presence of any outlier payments.

The measure of both mean episode payments and median episode payments within the MSA was considered. We proposed to stratify by mean because it would provide more information on the variation in episode payments at the high end of the range of payments. We are interested in the lower payment areas for the purpose of informing decisions about potential future model expansion. However, the CJR model is expected to have the greatest impact in areas with higher average episode payments.

The average episode payments used in this analysis were calculated based on the proposed episode definition for CJR using Medicare claims accessed through the Chronic Conditions Warehouse for 3 years with admission dates from July 1, 2011 through June 30, 2014. Episode payments were wage-adjusted using the FY 2014 hospital wage index contained in the FY 2014 IPPS Final Rule, downloaded at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Data-Files.html*. The adjusted payment was calculated by dividing the unadjusted payment by a factor equal to the sum of 0.3 plus the multiplicative product of 0.7 and the wage index value of the hospital where the LEJR was performed. We truncated the episode payment at the 99.9th percentile of the distribution ($135,000) to limit the impact of extreme outliers.

(b) MSA Population Size

The second dimension proposed for the CJR selection strata is the number of persons in the MSA. In deciding how best to incorporate the dimensions of urban density and availability of medical resources, a variety of measures were considered, including overall population in the included counties, overall population in the core area of the MSA, population over the age of 65 in the MSA, the number of hospital beds and the number of Medicare FFS LEJR procedures in a year. The reason we decided to include this dimension in the strata definition is that these factors are believed to be associated with the availability of resources and variations in practice and referral patterns by the size of the healthcare market. When examined, these alternative measures were all very highly correlated with one another, which allowed the use of one of these measures to be able to substitute for the others in the definition of the stratum. From these alternative approaches, we choose to use MSA population. In operationalizing this measure, MSAs were classified according to their 2010 census population.

(c) Analysis of Strata

The two proposed domains, MSA population and MSA historic LEJR episode spending, were examined using a K-Means factor analysis. The purpose of this factor analysis was to inform the process of which cut points most meaningfully classify MSAs. Factor analysis attempts to identify and isolate the underlying factors that explain the data using a matrix of associations. Factor analysis is an interdependence technique. Essentially, variables are entered into the model and the factors (or clusters) are identified based on how the input variables correlate to one another. The resulting clusters of MSAs produced by this methodology suggested natural cut points for average episode payments at $25,000 and $28,500. While not intentional, these divisions correspond roughly to the 25th and 75th percentiles of the MSA distribution. Cut points based on these percentiles seemed reasonable from statistical and face validity perspectives in the sense that they created groups that included an adequate number of MSAs and a meaningful range of costs.

As a result of this analysis, we classified MSAs according to their average LEJR episode payment into four categories based the on the 25th, 50th and 75th percentiles of the distribution of the 196 potentially selectable MSAs as determined in the exclusion rules as applied in the proposed rule (80 FR 41198). This approach ranks the MSAs relative to one another and creates four equally sized groups of 49. The population distribution was divided at the median point for the MSAs eligible for potential selection as determined and defined in the proposed rule. This resulted in MSAs being divided into two equal groups of 98. The characteristics of the resulting strata are shown in Table 2.

TABLE 2—SUMMARY POPULATION AND EPISODE PAYMENT STATISTICS BY MSA GROUP

| | Payment in lowest quarter | Payment in 2nd lowest quarter | Payment in 3rd lowest quarter | Payment in highest quarter | Total eligible |
|---|---|---|---|---|---|
| MSAs deemed eligible in the proposed rule (80 FR 41198) with population less than median: | | | | | |
| Number of Eligible MSAs | 33 | 19 | 22 | 24 | 98 |
| Average of Population | 251,899 | 238,562 | 268,331 | 254,154 | 253,554 |
| Minimum MSA Population | 96,275 | 55,274 | 106,331 | 96,024 | 55,274 |
| Maximum MSA Population | 425,790 | 416,257 | 424,858 | 428,185 | 428,185 |
| Average Episode Payments ($) | $22,994 | $25,723 | $27,725 | $30,444 | $26,410 |
| Minimum Episode Payments | $18,440 | $24,898 | $26,764 | $29,091 | $18,440 |
| Maximum Episode Payments | $24,846 | $26,505 | $28,679 | $32,544 | $32,544 |
| MSAs deemed eligible in the proposed rule (80 FR 41198) with population more than median: | | | | | |
| Number of Eligible MSAs | 16 | 30 | 27 | 25 | 98 |
| Average of Population | 1,530,083 | 1,597,870 | 1,732,525 | 2,883,966 | 1,951,987 |
| Minimum MSA Population | 464,036 | 436,712 | 434,972 | 439,811 | 434,972 |
| Maximum MSA Population | 4,335,391 | 5,286,728 | 12,828,837 | 19,567,410 | 19,567,410 |
| Average Episode Payments ($) | $23,192 | $25,933 | $27,694 | $30,291 | $27,082 |

TABLE 2—SUMMARY POPULATION AND EPISODE PAYMENT STATISTICS BY MSA GROUP—Continued

| | Payment in lowest quarter | Payment in 2nd lowest quarter | Payment in 3rd lowest quarter | Payment in highest quarter | Total eligible |
|---|---|---|---|---|---|
| Minimum Episode Payments | $16,504 | $25,091 | $26,880 | $28,724 | $16,504 |
| Maximum Episode Payments | $24,819 | $26,754 | $28,659 | $33,072 | $33,072 |
| Total Eligible MSAs | 49 | 49 | 49 | 49 | |

**Note:** Population and episode payment means are unweighted averages of the MSA values within each of the eight MSA groups.

Please refer to the addenda for this final rule for information on the non-excluded MSAs, their wage adjusted average LEJR episode spending, their population and their resultant group assignment at: *http://innovation.cms.gov/initiatives/cjr/*.

(3) Factors Considered But Not Used in Creating Proposed Strata

In addition to the two dimensions we proposed to use for the selection groups previously discussed, a variety of possible alternative measures and dimensions were considered. Many of these variables are considered to be important but it was believed that it was important to have a fairly straightforward and easily understandable stratum definition. Simplicity, by definition, required that only the most important variables would be used. If a market characteristic under consideration was correlated with one of the chosen dimensions or it was believed that variations in the characteristic could be adequately captured by random selection within the strata, is was not prioritized for inclusion.

Some of the factors considered that we did not propose as dimensions are—

- Measures associated with variation in practice patterns associated with LEJR episodes. In considering how to operationalize this measure, a number of alternatives were considered including total PAC LEJR payments in an MSA, percent of LEJR episodes with a SNF claim in an MSA, percent of LEJR episodes with an initial discharge to HHA, percent of LEJR episodes with an Inpatient rehabilitation facility (IRF) claim, and percent of LEJR episodes with claims for two or more types of PAC providers;
- Measures associated with relative market share of providers with respect to LEJR episodes;
- Healthcare supply measures of providers and suppliers in the MSA including counts of IRF beds, SNF beds, hospital beds, and number of orthopedic surgeons;
- MSA level demographic measures such as; average income, distributions of population by age, gender or race, percent dually eligible, percent of population with specific health conditions or other demographic composition measures; and
- Measures associated with the degree to which a market might be more capable or ready to implement care redesign activities. Examples of market level characteristics that might be associated with anticipated ease of implementation include the MSA-level EHR meaningful use levels, managed care penetration, ACO penetration and experience with other bundling efforts.

It should be noted that, while these measures were not proposed to be part of the selection strata, we acknowledge that these and other market-level factors may be important to the proper understanding of the evaluation of the impact of CJR. It is the intention that these and other measures will be considered in determining which MSAs are appropriate comparison markets for the evaluation as well as considered for possible subgroup analysis or risk adjustment purposes. The evaluation will include beneficiary, provider, and market level characteristics in how it examines the performance of this proposed model.

(4) Sample Size Calculations and the Number of Selected MSAs

Analyses of the necessary sample size to facilitate a robust statistical analysis of CJR's effects led us to conclude that we needed to include between 50 and 100 MSAs of the 384 MSAs with eligible LEJR episodes to participate in CJR and we proposed to select 75 MSAs. As previously discussed, the proposed revision of the MSA exclusion rules resulted in 8 of the previously selected MSAs now being considered excluded, leading to their removal from the model. The resulting number of selected MSAs, 67, is still within the acceptable range for an MSA count as determined by our analysis. The number and method of selection of these original 75 MSAs from the 8 proposed groups is addressed in the following section. In finalizing this approach, we are undertaking a test in as few markets as possible while still allowing us to be confident in our results and to be able to generalize from the model to the larger national context. We discuss the assumptions and modeling that went into our proposal later in this section.

In calculating the necessary size of the model, a key consideration was ensuring that the model would have sufficient power to be able to detect the desired size impact. The larger the anticipated size of the impact, the fewer MSAs we would have to sample in order to observe it. However, a model sized to be able to only detect large impacts runs the risk of not being able to draw conclusions if the size of the change is less than anticipated. The measure of interest used in estimating sample size requirements for the CJR model was wage-adjusted total episode spending. To measure wage-adjusted total episode spending, we used the 3 year data pull also used for the average regional episode spending estimation that covers LEJR episodes with admission dates from July 1, 2011 through June 30, 2014. For the purposes of the sample size calculation the impact estimate assumed we wanted to be able to detect a 2 percent reduction in wage adjusted episode spending after 1 year of experience. This amount was chosen because it is the anticipated amount of the discount we proposed to apply to target prices in CJR.

The next consideration in calculating the necessary sample size is the degree of certainty we will need for the statistical tests that will be performed. In selecting the right sample size, there are two types of errors that need to be considered ''false negatives'' and ''false positives''. A false positive occurs if a statistical test concludes that the model was successful when it was, in fact, not. A false negative occurs if a statistical test fails to find statistically significant evidence that the model was successful, but it was, in fact, successful. In considering the minimum sample size needs of a model, a standard guideline in the statistical literature suggests calibrating statistical tests to generate no more than a 5 percent chance of a false positive and selecting the sample size to ensure no more than a 20 percent

chance of a false negative. In contrast, the proposed sample size for this project was based on a 20 percent chance of a false positive and a 30 percent chance of a false negative after one year of episodes in order to be as conservative as was practicable. A greater degree of certainty will be available with additional years of data.

A third consideration in the sample size calculation was the appropriate unit of selection and whether it is necessary to base the calculation on the number of MSAs, the number of hospitals, or the number of episodes. As discussed later in this section, we are proposing to base the sample size calculation at the MSA level.

The CJR model is a nested comparative study, which has two key features. First, the unit of assignment (to treatment and comparison groups) is an identifiable group; such groups are not formed at random, but rather through some physical, social, geographic, or other connection among their members. Second, the units of observation are members of those groups. In such designs, the major analytic problem is that there is an expectation for a positive correlation (intra-class correlation (ICC)) among observations of members of the same group (MSA). The ICC reflects an extra component of variance attributable to the group above and beyond the variance attributable to its members. This extra variation will increase the variance of any aggregate statistic beyond what would be expected with random assignment of beneficiaries or hospitals to the treatment group.

In determining the necessary sample size, we need to take into consideration the degrees of freedom. As part of this process, we examined the number of beneficiaries, the number of hospitals, and the number of MSAs and the level of correlation in episode payments between each level. For example, while each beneficiary has their own episode expenditure level, there are commonalities between those expenditure amounts at the hospital level, based on hospital-specific practice and referral patterns. The number of degrees of freedom needed for any aggregate statistic is related to the number of groups (MSAs or hospitals), not the number of observations (beneficiary episodes). If we were to base the determination of the size of the model on beneficiary episodes where correlation exists, we would have an inflated false positive error rate and would overstate the impact of the model. We empirically examined the level of correlation between beneficiaries and hospitals and between hospitals and MSAs and determined that the correlation was high enough to be of concern and necessitate an MSA level unit of selection.

Using the previous assumptions, a power calculation was run which indicated we would need between 50 and 150 treatment MSAs to be able to reliably detect a 2 percent reduction in payments after 1 year. The lower end of this range assumed that our evaluation approach could substantially reduce variation through regression adjustment and other types of statistical modeling. We anticipated that we would have adequate statistical power based on prior research results, but wanted to ensure that we did not have to achieve the ''best possible'' results from such modeling in order to draw conclusions. In order to allow for some degree of flexibility we proposed the selection of 75 MSAs. We narrowed the acceptable range to between 50 and 100 MSAs rather than 50 to 150 MSAs, based on the assumption that we will be able to substantially improve our estimates through modeling, and then chose a number near the middle of this reduced range. Due to the revised exclusion rules, we are proceeding with 67 MSAs, which we believe will provide adequate statistical power.

In assessing to what degree regression adjustment and other statistical adjustments could reduce the number of MSAs needed to generate statistically reliable results, it should be noted that calculations are based on the actual Medicare payments associated with episodes. Thus, the variation in payments associated with MS–DRG case mix, or other reasons are already captured in the methodology.

(5) Method of Selecting MSA

As previously discussed, we selected 75 MSAs from our proposed 8 selection groups and subsequently reduced this number to 67. In performing the initial MSA selection, we examined and considered a number of possible approaches including equal selection in each of the eight groups, equal selection in the four payment groups, selection proportionate to the number of MSAs in each group, and a number of approaches that differentially weighted the payment categories.

After consideration, we proposed a methodology that proportionally under-weighted more efficient MSAs and over-weighted more expensive MSAs was the most appropriate approach to fulfilling the overall priorities of this model to increase efficiencies and savings for LEJR cases while maintaining or improving the overall quality of care. This approach made MSAs in the lowest spending category less likely to be selected for inclusion. We thought this appropriate because the MSAs in the lowest expenditure areas have the least room for possible improvement and are already performing relatively efficiently compared to other geographic areas, which means that experience with the model in these areas may be relatively less valuable for evaluation purposes. At the same time, we believed it was important to include some MSAs in this group in order to assess the performance of this model in this type of circumstance. We also believed it was appropriate for higher payment areas to be disproportionately included because they are most likely to have significant room for improvement in creating efficiencies. We expect more variation in practice patterns among the more expensive areas. There are multiple ways an MSA can be more relatively expensive, including through outlier cases, higher readmission rates, greater utilization of physician services, or through PAC referral patterns. A larger sample of MSAs within the higher payment areas will allow for us to observe the impact of the CJR model on areas with these various practice patterns in the baseline period.

The method of disproportionate selection between the strata used was to choose 30 percent of the MSAs in the two groups in the bottom quarter percentile of the payment distribution, 35 percent of the MSAs in the two groups in the second lowest quartile, 40 percent in the third quartile, and 45 percent in the highest episode payment quartile. This proportion resulted in the selection of the 75 originally selected MSAs out of the 196 eligible. The number of MSAs originally chosen as well as the final selection counts within the eight selection groups is shown in Table 3.

TABLE 3—NUMBER OF MSAS TO BE CHOSEN FROM THE EIGHT SELECTION GROUPS

| | Payment in lowest quarter | Payment in 2nd lowest quarter | Payment in 3rd lowest quarter | Payment in highest quarter | Total eligible MSAs |
|---|---|---|---|---|---|
| Selection Proportion | 30% | 35% | 40% | 45% | |
| Less Than Median Population (Group #) | (1) | (2) | (3) | (4) | |
| Number Eligible MSAs per Proposed Rule (80 FR 41198) | 33 | 19 | 22 | 24 | 98 |
| Proportion x Number | 9.9 | 6.65 | 8.8 | 10.8 | |
| Number initially selected from group | 10 | 7 | 9 | 11 | 37 |
| Number finally selected from group | 8 | 6 | 8 | 11 | 33 |
| More Than Median Population (Group #) | (5) | (6) | (7) | (8) | |
| Number Eligible MSAs per NPRM | 16 | 30 | 27 | 25 | 98 |
| Proportion x Number | 4.8 | 10.5 | 10.8 | 11.25 | |
| Number initially selected from group | 5 | 11 | 11 | 11 | 38 |
| Number finally selected from group | 5 | 10 | 9 | 10 | 34 |
| Total Eligible MSAs per Proposed Rule (80 FR 41198) | 49 | 49 | 49 | 49 | 196 |
| Number initially selected | 15 | 18 | 20 | 22 | 75 |
| Number finally selected from group | 13 | 16 | 17 | 21 | 67 |

We selected the proposed MSAs for the CJR model through random selection. In the proposed method of selection, each MSA was assigned to one of the eight selection groups previously identified. Based on this sampling methodology, SAS Enterprise Guide 7.1 software was used to run a computer algorithm designed to randomly select MSAs from each strata. SAS Enterprise Guide 7.1 and the computer algorithm used to conduct selection represents an industry standard for generating advanced analytics and provides a rigorous, standardized tool by which to satisfy the requirements of randomized selection. The key SAS commands employed include a ''PROC SURVEYSELECT'' statement coupled with the ''METHOD=SRS'' option used to specify simple random sampling as the sample selection method. A random number seed was generated for each of the eight strata by using eight number seeds corresponding to birthdates and anniversary dates of parties present in the room. The random seeds for stratum one through eight were as follows: 907, 414, 525, 621, 1223, 827, 428, 524. Note that no additional stratification was used in any of the eight groupings so as to produce an equal probability of selection within each of the eight groups. For more information on this procedure and the underlying statistical methodology, please reference SAS support documentation at: *http://support.sas.com/documentation/cdl/en/statug/63033/HTML/default/viewer.htm#statug_surveyselect_sect003.htm/* We also considered a potential alternative approach to this random selection in which we would generate a starting number within SAS and then choose every third MSA within a group starting at this point until the relevant number of MSAs were chosen. We opted to not utilize this feature for simplicity's sake and alignment with other randomization methodologies used for CMS models.

The selection of an MSA means that all hospitals are included whose address associated with their CCN is physically located anywhere within the counties that make up the MSA. By definition, the entire county is included in an MSA and hospitals that are in the relevant counties will be impacted even if they are not part of the core urban area.

We stated in the proposed rule, should the methodology we propose in this rule change as a result of comments received during the rulemaking process, it could result in different areas being selected for the model. In such an event, we would apply the final methodology and announce the selected MSAs in the final rule. Therefore we sought comment from all interested parties in every MSA on the randomized selection methodology proposed in this section.

The following is a summary of the comments received and our responses.

*Comment:* Two commenters raised concerns regarding the number of MSAs selected for inclusion in the model. One noted that, given the range between 50 and 150 treatment MSAs to be able to reliably detect a 2 percent reduction in payments, CMS could drop some of the 75 selected MSAs without jeopardizing the ability to produce generalizable results from the CJR model. Another commenter suggested that the approach to the model should focus on an intense analysis within fewer markets prior to expansion into a larger representative sample.

*Response:* As discussed in the proposed rule, a variety of considerations were made in the determination of what would be an appropriate sample size. The initially proposed 75 MSAs represented the 25 percentage points of the acceptable range of MSAs to be included as determined by sample size calculations. We believe that using a number near the bottom of the range would represent an unnecessary risk to our ability to draw conclusions from the model in a timely manner. While we would prefer to have 75 MSAs in the model in order to increase the likelihood of being able to make definitive statements about the impact of the model at an earlier date, we believe the loss of the 8 MSAs now deemed not eligible for selection constitutes an acceptable risk.

With respect to the request to test the model in a limited pool of MSAs prior to testing it in the full set of selected MSAs, we believe that the testing of this model broadly is crucial to achieving the model's desired objectives and does not believe that proceeding in a few test MSAs prior to testing it in a broader set of MSAs would yield the same degree of information in the same time period.

*Comment:* A commenter was concerned that the selection strata used did not use MSA-level demographic measures in its selection process, including distributions of population by age, gender, or race; percent of population dually-eligible; percent of population with specific health conditions or other demographic composition measures. They believed these areas associated with more at-risk populations should be represented less in the selection. Another commenter did not question the selection strata but contended that the random selection happened to choose fewer areas with lower income and minority Medicare beneficiaries than they thought desirable. They specifically inquired

after the lack of inclusion of MSAs in Alabama and Georgia.

*Response:* We considered but ultimately decided against including the dimension based on the demographic characteristics of an MSA incorporated in the selection strata. If we were to have done so, the purpose would have been to ensure an adequate representation along the range of these demographic considerations rather than to eliminate them from possible selection. While these factors are not explicitly part of the selection strata used, the resulting selected MSAs provide an adequate representation of a variety of circumstances including the experiences of areas with a higher degree of non-white populations, MSAs with a range in average income level, and other key characteristics. With regards to the specific concerns regarding under-representation in the MSAs selected from specific states, we note that Alabama, which has relatively high episode costs, had three of its seven eligible MSAs selected while Georgia, whose MSAs had episode payments that indicated relatively more efficient patterns of care, had two of its six eligible MSAs selected. As such, we believe that the experiences of these states and MSAs that are similar in nature to them are adequately represented in the selected MSAs.

*Comment:* A commenter requested clarification regarding how to interpret which MSAs are included in the model.

*Response:* We refer readers to Table 4 for a final list of the MSAs that are in the CJR model.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal, with modification to include 67 of the originally selected 75 MSAs. We used updated BPCI participation level information in the application of the MSA exclusion rules for this final rule, resulting in the exclusion of an additional 8 MSAs that were previously selected. We note that we are posting the list of the participant hospitals in the selected MSAs on the CJR Web site at *http://innovation.cms.gov/initiatives/CJR/*. This list will be updated throughout the model, to account for circumstances such as hospital mergers, BPCI termination, and new hospitals within the selected MSAs.

We set forth this final policy in § 510.100 and § 510.105.

TABLE 4—MSAS INCLUDED IN THE CJR MODEL

| MSA | MSA Name |
|---|---|
| 10420 | Akron, OH |
| 10740 | Albuquerque, NM |
| 11700 | Asheville, NC |
| 12020 | Athens-Clarke County, GA |
| 12420 | Austin-Round Rock, TX |
| 13140 | Beaumont-Port Arthur, TX |
| 13900 | Bismarck, ND |
| 14500 | Boulder, CO |
| 15380 | Buffalo-Cheektowaga-Niagara Falls, NY |
| 16020 | Cape Girardeau, MO-IL |
| 16180 | Carson City, NV |
| 16740 | Charlotte-Concord-Gastonia, NC-SC |
| 17140 | Cincinnati, OH-KY-IN |
| 17860 | Columbia, MO |
| 18580 | Corpus Christi, TX |
| 19500 | Decatur, IL |
| 19740 | Denver-Aurora-Lakewood, CO |
| 20020 | Dothan, AL |
| 20500 | Durham-Chapel Hill, NC |
| 22420 | Flint, MI |
| 22500 | Florence, SC |
| 23540 | Gainesville, FL |
| 23580 | Gainesville, GA |
| 24780 | Greenville, NC |
| 25420 | Harrisburg-Carlisle, PA |
| 26300 | Hot Springs, AR |
| 26900 | Indianapolis-Carmel-Anderson, IN |
| 28140 | Kansas City, MO-KS |
| 28660 | Killeen-Temple, TX |
| 30700 | Lincoln, NE |
| 31080 | Los Angeles-Long Beach-Anaheim, CA |
| 31180 | Lubbock, TX |
| 31540 | Madison, WI |
| 32820 | Memphis, TN-MS-AR |
| 33100 | Miami-Fort Lauderdale-West Palm Beach, FL |
| 33340 | Milwaukee-Waukesha-West Allis, WI |
| 33700 | Modesto, CA |
| 33740 | Monroe, LA |
| 33860 | Montgomery, AL |
| 34940 | Naples-Immokalee-Marco Island, FL |
| 34980 | Nashville-Davidson–Murfreesboro–Franklin, TN |
| 35300 | New Haven-Milford, CT |
| 35380 | New Orleans-Metairie, LA |
| 35620 | New York-Newark-Jersey City, NY-NJ-PA |
| 35980 | Norwich-New London, CT |
| 36260 | Ogden-Clearfield, UT |
| 36420 | Oklahoma City, OK |
| 36740 | Orlando-Kissimmee-Sanford, FL |
| 37860 | Pensacola-Ferry Pass-Brent, FL |
| 38300 | Pittsburgh, PA |
| 38940 | Port St. Lucie, FL |
| 38900 | Portland-Vancouver-Hillsboro, OR-WA |
| 39340 | Provo-Orem, UT |
| 39740 | Reading, PA |
| 40980 | Saginaw, MI |
| 41860 | San Francisco-Oakland-Hayward, CA |
| 42660 | Seattle-Tacoma-Bellevue, WA |
| 42680 | Sebastian-Vero Beach, FL |
| 43780 | South Bend-Mishawaka, IN-MI |
| 41180 | St. Louis, MO-IL |
| 44420 | Staunton-Waynesboro, VA |
| 45300 | Tampa-St. Petersburg-Clearwater, FL |
| 45780 | Toledo, OH |
| 45820 | Topeka, KS |
| 46220 | Tuscaloosa, AL |
| 46340 | Tyler, TX |
| 48620 | Wichita, KS |

*B. Episode Definition for the CJR Model*

1. Background

CJR model is an episode payment model, focused on incentivizing health care providers to improve the efficiency and quality of care for an episode of care as experienced by a Medicare beneficiary by bundling payment for services furnished to the beneficiary for an episode of care for a specific clinical condition over a defined period of time. Key policies of such a model include the definition of episodes of care. Episodes of care have two significant dimensions—(1) A clinical dimension that describes what clinical conditions and associated services comprise the episode; and (2) a time dimension that describes the beginning, middle, and end of an episode. We present our proposals, summarize public comments and provide our responses, and finalize the policies for these two dimensions of CJR episodes in this section.

2. Clinical Dimension of Episodes of Care

a. Definition of the Clinical Conditions Included in the Episode

As discussed previously in section I.A. of this final rule, we identified LEJR episodes, primarily hip and knee replacements, as the focus of this model. In the proposed rule, we stated our belief that a straightforward approach for hospitals and other providers to identify Medicare beneficiaries in this payment model is important for the care redesign that is required for model success, as well as to operationalize the proposed payment and other model policies.

The vast majority of LEJRs are furnished in the inpatient hospital setting, with a small fraction of partial knee replacements occurring in the hospital outpatient department (HOPD) setting. Most of the Current Procedural Terminology (CPT) codes that physicians report for LEJR are on the hospital OPPS inpatient only list. The CY 2015 OPPS inpatient only list is Addendum E of the CY 2015 Hospital Outpatient Prospective Payment—Final Rule with Comment Period, which is available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-*

*1613-FC.html*. Thus, under current FFS payment policy, Medicare pays hospitals for the facility services required for most LEJR procedures only when those procedures are furnished in the inpatient hospital setting. Therefore, in our proposal we stated our belief that an episode payment model most appropriately focuses around an inpatient hospitalization for these major surgical procedures, as there is little opportunity for shifting the procedures under this model to the outpatient setting.

We noted further that LEJRs are paid for under the IPPS through the following two Medicare Severity-Diagnosis Related Groups (MS–DRGs):

- MS–DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)).
- MS–DRG 470 (Major joint replacement or reattachment of lower extremity without MCC).

Multiple International Classification of Diseases, 9th Revision, Clinical Modification (ICD–9–CM) procedure codes that describe LEJR procedures and other less common lower extremity procedures group to these MS–DRGs, with their percentage distribution within the IPPS MS–DRGs 469 and 470 for the past 4 years outlined in Table 5.

TABLE 5—DISTRIBUTION OF HOSPITAL CLAIMS FOR ICD–9–CM PROCEDURE CODES MAPPING TO MS–DRGS 469 AND 470

| ICD–9–CM procedure code | Code descriptor | FY 2014 (%) | FY 2013 (%) | FY 2012 (%) | FY 2011 (%) |
|---|---|---|---|---|---|
| 81.54 | Total knee replacement | 57 | 58 | 58 | 58 |
| 81.51 | Total hip replacement | 30 | 29 | 29 | 28 |
| 81.52 | Partial hip replacement | 12 | 13 | 13 | 14 |
| 81.56 | Total ankle replacement | 0 | 0 | 0 | 0 |
| 00.85 | Resurfacing hip, total, acetabulum and femoral head | 0 | 0 | 0 | 0 |
| 00.86 | Resurfacing hip, partial, femoral head | 0 | 0 | 0 | 0 |
| 00.87 | Resurfacing hip, partial, acetabulum | 0 | 0 | 0 | 0 |
| 84.27 | Lower leg or ankle reattachment | 0 | N/A | N/A | N/A |
| 84.28 | Thigh reattachment | N/A | N/A | N/A | 0 |

**Note:** Percentages or claim counts with "N/A" had no claims. Percentages of 0% represent less than 0.5% of total claims.

Additionally, we noted that there are various types of claims-based information available to CMS, hospitals, and other providers, that could be used to identify beneficiaries in the model who receive LEJRs, including the MS–DRGs for the acute care hospitalization for the procedure, the ICD–9–CM procedure code on the hospital claim, or the CPT code(s) reported by the orthopedic surgeon who furnishes the surgical procedure. While we could utilize ICD–9–CM procedure codes or CPT codes to identify beneficiaries included in the model, over 85 percent of procedures that group to MS–DRGs 469 and 470 are hip or knee replacements. Additionally, the hospitals that would be participating in this model receive payment under the IPPS, which is not determined by CPT codes and is based on clinical conditions and procedures that group to MS–DRGs. Finally, our review of the other low volume procedures that group to these same MS–DRGs, aside from total or partial hip and knee replacements, did not suggest that there is significant clinical or financial heterogeneity within these two MS–DRGs such that we would need to define care for included beneficiaries by ICD–9–CM procedure codes.

Therefore, we proposed that an episode of care in the CJR model would be triggered by an admission to an acute care hospital stay (hereinafter ''the anchor hospitalization'') paid under MS–DRG 469 or 470 under the IPPS during the model performance period. This approach offers operational simplicity, for providers and CMS, and is consistent with the approach taken by the BPCI initiative to identify beneficiaries whose care is included in the LEJR episode for that model. We sought public comments on this proposal to define the clinical conditions that are the target of CJR.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters expressed support for CMS' proposal to define the clinical conditions included in the CJR model episode by discharge from an anchor hospitalization that is paid under MS–DRG 469 or 470 under the IPPS, although a commenter claimed that the cases within each MS–DRG are too heterogeneous to form the basis of a single target price as CMS proposed. The commenter added that risk adjustment could take the form of case exclusions, stratifying cases within each MS–DRG to create separate target prices, or adjusting the target prices based on principal procedure and patient characteristics. Most commenters recommended that CMS limit the model to a subset of beneficiaries that were discharged from these two MS–DRGs, effectively excluding certain cases as form of risk adjustment to reduce the heterogeneity of the cases in the model. The commenters asserted that CMS' proposal, which did not include risk adjustment beyond setting different target prices for episodes based on discharges from the two different MS–DRGs, failed to take into consideration the variability of service needs of beneficiaries discharged from these two MS–DRGs related to the specific procedure performed, the elective or urgent/emergent nature of the procedure, and the beneficiary's clinical and demographic characteristics, including underlying medical conditions and age. Several commenters recommended that CMS define the clinical conditions included in the model by discharges only from MS–DRG 470, claiming that these beneficiaries represented a more homogeneous group that had less complex health care needs. Some commenters urged CMS to define the clinical conditions in the model based on specific MS–DRG and ICD–9–CM procedure code combinations for hip and knee arthroplasty, and stated that CMS should exclude low volume procedures that also map to MS–DRGs 469 and 470 including ankle replacement; lower leg, ankle, and thigh reattachment; and hip resurfacing procedures. The commenters stated that these uncommon procedures display substantial heterogeneity in the clinical characteristics and needs of the beneficiary, as well as the associated Medicare payment for services throughout an episode. They contended that the rationale for CMS' proposal addressed hip and knee replacement in

detail but failed to consider the different PAC patterns of other beneficiaries discharged from the same MS–DRGs but who had different surgical procedures. A commenter recommended that CMS specifically exclude episodes for conversion total joint arthroplasty procedures, which require removal of previously placed hardware followed by THA or TKA in the same operative session, arguing that these beneficiaries had more complex needs.

Many commenters recommended that CMS define the clinical conditions in the model as episodes specific to elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures. The commenters stated that this group of beneficiaries is more homogeneous than beneficiaries undergoing emergent joint replacement procedures for hip fractures or undergoing the other low volume procedures that map to the MS–DRGs. Given that CMS did not propose risk adjustment under the model based on procedure or patient characteristics, the commenters contended that limiting the model to these clinical conditions, that represent about 85 percent of beneficiaries discharged for the two MS–DRGs, would provide a sufficient number of cases to test LEJR episode payment and allow hospitals to create efficient, effective clinical pathways for these beneficiaries. The commenters also observed that CMS' quality measures, specifically the THA/TKA readmissions and complications measures, as well as the voluntary data collection for patient-reported outcomes, would represent only the quality of care for beneficiaries undergoing elective THA and TKA procedures. Several commenters recommended that CMS only include episodes in the model for beneficiaries discharged from MS–DRG 469 or 470 whose data would be used to determine the model's quality measures for the participant hospital.

The commenters suggested several different approaches to defining the clinical conditions included in the model as elective THA or TKA. One approach would be to eliminate from the model beneficiaries with reported ICD–9–CM procedure codes other than THA or TKA, and then further exclude some remaining beneficiaries with ICD–9–CM codes for hip fracture on their claim for the anchor hospitalization. Other commenters asserted that CMS should exclude the beneficiaries receiving the low volume procedures as well as those receiving partial hip arthroplasty (PHA) procedures. The commenters pointed out that almost all of the beneficiaries receiving PHA would have hip fractures and observed that the average Medicare episode payment for beneficiaries undergoing PHA was similar to beneficiaries discharged from MS–DRG 469 or 470 with hip fracture diagnoses, almost twice the payment for beneficiaries undergoing elective THA and TKA. Several commenters presented analyses that demonstrated that beneficiaries with hip fracture, regardless of their discharge from MS–DRG 469 or 470, when compared to beneficiaries with elective procedures, experience twice as high readmissions and PAC utilization rates, as well as higher morbidity and mortality.

The commenters in favor of excluding clinical conditions involving hip fractures from the model stated that the number of hip fracture cases treated by individual hospitals can vary significantly on an annual basis, both due to random variation and practice or population changes. Moreover, different hospitals provide care for different percentages of beneficiaries with hip fracture and, according to some commenters, academic medical centers and small hospitals care for disproportionate percentages of these cases for reasons of medical complexity and the urgent nature of the procedure, respectively, because beneficiaries who fall and experience a hip fracture are commonly transported to their local hospital for emergent treatment. Furthermore, in addition to the variation a hospital itself may experience regarding the percentage of hip fracture cases, which could lead to the hospital-specific historical data used for a portion of the target price to not be reflective of the health care needs of the hospital's episode population in a given performance year, some commenters observed that the increasing percentage of the target price contributed by regional data exacerbated their concerns. Hospitals in a region that care for a disproportionately high percentage of hip fracture patients compared to the regional average would be disadvantaged due to the more intense service needs of hip fracture patients, whereas hospitals caring for a disproportionately low percentage of hip fracture patients compared to the regional average would be advantaged. The commenters contended that excluding clinical conditions involving hip fractures from the CJR model would ensure homogeneity in the beneficiaries in the model such that hospitals would be treated fairly with respect to episode pricing based on the hospital-specific and regional historical CJR episode data for only those beneficiaries undergoing elective THA and TKA.

*Response:* We appreciate the analyses and suggestions provided by the commenters regarding the most appropriate approach to defining the clinical conditions included in the CJR model. As discussed in section III.C.4.b. of this final rule, we have decided to risk stratify the target price for each MS–DRG-anchored episode based on a beneficiary's hip fracture status. This policy allows us to maintain beneficiaries who receive LEJR procedures due to hip fractures in the CJR model, while acknowledging their typically greater health care needs by providing a target price that is based on payment for services furnished in the historical CJR episode data for Medicare beneficiaries with hip fractures in order to account for a significant amount of beneficiary-driven episode expenditure variation. While beneficiaries with hip fractures may present a more costly population due to greater health care needs, and CJR participant hospitals may vary in their percentages of such beneficiaries, we believe that beneficiaries with hip fracture have the potential to benefit substantially from the care pathways and improved care coordination among providers and suppliers that is incentivized by an episode payment model. In addition, we believe there are opportunities for increased efficiency in the care of beneficiaries with hip fracture who receive LEJR procedures with respect to appropriate PAC utilization and care coordination and management of chronic conditions that may be affected by the LEJR procedure or post-surgical care. Thus, we are finalizing our proposal to include LEJR procedures that result from hip fracture treatment in the clinical conditions that are part of the CJR model episodes, rather than limiting the model conditions to only elective THA and TKA.

We are also finalizing our proposal to include clinical conditions represented by discharge from both MS–DRG 469 and 470 in the CJR model. We believe that providing separate prices for episodes anchored by the two different MS–DRGs accounts for the differences in typical health care needs of the two groups of beneficiaries, specifically the higher IPPS payment for the anchor hospitalization for beneficiaries discharged under MS–DRG 469, as well as the pattern of service utilization for this group of beneficiaries in the 90 days following discharge.

Additionally, we are finalizing our proposal to include any lower extremity joint procedure that results in discharge from MS–DRG 469 or 470 in the CJR

model, including ankle replacement; lower leg, ankle, and thigh reattachment; and hip resurfacing procedures. While the model beneficiaries with these less common clinical conditions are likely to be a small number at any specific participant hospital, they too may benefit from care redesign resulting in improved care coordination and quality that are goals of the CJR model. These beneficiaries share the experience of undergoing major surgical procedures involving the lower extremity with the majority of CJR model beneficiaries undergoing THA or TKA, and they too are likely to require PAC services and care coordination and management of chronic medical conditions to optimize their return to function. We expect that the Medicare actual episode payments for these clinical conditions may be highly variable given the small numbers and variable clinical characteristics of these beneficiaries such that historical episode data may have little predictive power regarding the actual episode payment for the beneficiaries in a model performance year. We do not believe this small number of beneficiaries will put participant hospitals at undue financial risk and further note that our payment policies as discussed in section III.C.3.c. and III.C.8. of this final rule provide a pricing adjustment for high payment episodes and limit hospital financial responsibilities to provide participant hospitals with additional protections.

We note that our final policy to include all clinical conditions that result in a discharge from MS–DRGs 469 or 470 in the CJR model allows us to continue to rely on MS–DRGs to define the clinical conditions included in the LEJR episode being widely tested under the CJR model, consistent with the BPCI methodology to define clinical conditions included in 48 different episodes based on the MS–DRGs for the anchor hospitalization. This approach provides greater certainty from the perspective of participant hospitals or CMS regarding the clinical conditions included in episodes, since the discharge MS–DRG is the defining parameter, and includes the greatest number of beneficiaries with similar clinical conditions in the CJR model test.

*Comment:* Several commenters urged CMS to include in the CJR model LEJR procedures where the procedure that would result in a beneficiary's discharge from MS–DRG 469 or 470 if furnished in the inpatient hospital setting is furnished in the HOPD, ambulatory surgical center (ASC), or other dedicated facility that is not an acute care facility. The commenters explained that elective procedures are commonly furnished in the HOPD, ASC, or other dedicated facilities that are not acute care facilities for certain beneficiaries covered by commercial insurance, while Medicare covers and pays for the procedures only when they are furnished in the inpatient hospital settings. The commenters disputed CMS' assertion in the proposed rule that there is little opportunity for shifting these procedures to the outpatient setting. They urged CMS to permit these LEJR procedures to be furnished to Medicare beneficiaries in other settings under the CJR model to improve episode efficiency. The commenters contended that physicians should be able to select the most appropriate inpatient hospital or outpatient setting based on the beneficiary's clinical condition.

*Response:* We appreciate the interest of the commenters in providing LEJR procedures under the CJR model to Medicare beneficiaries in alternative outpatient settings as a further opportunity to test strategies to provide high quality, efficient episode care for beneficiaries undergoing LEJR procedures. As we discussed in the proposed rule, the vast majority of LEJR procedures are furnished to Medicare beneficiaries in the inpatient hospital setting, with a small fraction of partial knee replacements occurring in the hospital outpatient department (HOPD). Most of the CPT codes that physicians report for LEJR procedures are on the hospital OPPS inpatient only list. Thus, under current Medicare program policy, Medicare generally pays hospitals for the facility services required for LEJR only when those procedures are furnished in the inpatient hospital setting. When we stated our belief in the proposed rule that an episode payment model such as the CJR model most appropriately focuses around an inpatient hospitalization for these major surgical procedures, as there is little opportunity for shifting the procedures under the model to the outpatient setting, we meant that this would be true under current Medicare policy. Because Medicare generally does not pay hospitals if procedures that would be assigned to MS–DRG 469 or 470 when furnished to inpatients are performed on hospital outpatients, these procedures would not be able to be shifted under the CJR model to the outpatient setting.

Because most LEJR procedures are on the OPPS inpatient list and CMS has, therefore, determined that Medicare beneficiaries require an inpatient hospitalization for payment of these procedures to hospitals, we are not changing the current inpatient only list designation of these LEJR procedures for the CJR model. CJR is an episode payment model, not a model designed to test different sites of services for procedures that CMS has thus far determined may not be safely performed on Medicare beneficiaries in the outpatient setting. Therefore, we are finalizing our proposal that the CJR model will continue to focus around an inpatient hospitalization for these major surgical procedures that result in a discharge from MS–DRG 469 or 470, and a procedure furnished in the outpatient setting will not be included in the model.

*Comment:* Several commenters maintained that because the procedures that result in discharge from MS–DRG 469 and 470 that define the clinical conditions included in the CJR model are on the OPPS inpatient only list, CMS should commit to keeping these procedures on the inpatient only list for the 5-year performance period of the model. The commenters pointed out that CMS has previously proposed, but not finalized, the removal of TKA procedures from the inpatient only list. The commenters stated that if any additional procedures that would otherwise result in discharge from one of the two MS–DRGs in the CJR model were to be removed from the inpatient only list during a year when the CJR model is being tested, the beneficiaries who would be included in the model performance year due to a procedure in the inpatient hospital setting would be sicker and more complex than those included in the historical CJR episodes used to set target prices. Therefore, the commenters reasoned that in order to establish target prices that reflect the health care needs and medical complexity of the CJR model beneficiaries in a model performance year, CMS should not remove any LEJR procedures from the OPPS inpatient only list until after the CJR model ends.

*Response:* We share the commenters' interest in ensuring that the historical CJR episodes that are used to set the target prices for CJR model episodes during a performance year reflect the health care needs and medical complexity of beneficiaries who are comparable to those actually included in the CJR model. If we were to remove an LEJR procedure from the OPPS inpatient only list at any point during the 5-year model test, we agree with the commenters that we would need to consider the effects of such a change on the CJR model pricing methodology, taking into consideration the characteristics of the beneficiaries expected to be in the model due to a

procedure furnished in the inpatient hospital setting after the change to the inpatient only list. If we concluded that changes in our pricing methodology were necessary because the beneficiaries in the historical CJR episodes used to set target prices would no longer be similar to those in the model performance year, we would propose such changes through notice and comment rulemaking.

*Comment:* Several commenters claimed that different states were testing different LEJR episode payment models. A commenter provided the example of Tennessee mandatory Medicaid bundles that utilize a different episode definition than proposed for the CJR model. The commenters encouraged CMS to move toward standard episode definitions for mandatory models, noting that each of the inconsistent mandatory models is being tested under the Innovation Center's statutory authority. The commenters contended that different episode payment models lead to excessive burden and greater cost for health care providers.

*Response:* We appreciate the perspective of the commenters on the challenges related to testing mandatory bundled payments with different episode definitions in the same community. We note, however, that the CJR model and various state episode payment models are all in various stages of testing and have used different strategies to arrive at the episode definitions for each model. By definition, models being tested have not yet produced evidence of improved quality and/or cost savings, so we lack the necessary evaluation results from various approaches to consider standardizing episode definitions. We believe there is value in testing different episode definitions given the current state of knowledge about bundled payment. We also believe that, regardless of the specific definitions for episodes that address the same clinical conditions in various different payment models, episode payment models share a common focus on improving the quality of care and increasing the efficiency of care through a variety of well-established strategies, such as increased communication among health care providers along the continuum of acute and PAC and improved care coordination and care management to promote beneficiary engagement that leads to adherence to treatment plans and, correspondingly, reductions in hospital readmissions and complications. As we gain more experience with episode payment models and examine their results, we will consider the potential benefits of standardizing episode definitions to the extent possible.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our proposal to define the clinical conditions included in the CJR model by admission to an IPPS hospital that results in a discharge from MS–DRG 469 or 470.

The final policies for defining the clinical conditions are set forth in § 510.100 and § 510.200.

b. Definition of Related Services Included in the Episode

For purposes of this model, as in BPCI, given the frequent comorbidities experienced by Medicare beneficiaries and the generally elective nature of LEJR, we are interested in testing inclusive episodes to incentivize comprehensive, coordinated patient-centered care for the beneficiary throughout the episode. We proposed to exclude only those Medicare items and services furnished during the episode that are unrelated to LEJR procedures based on clinical justification. During our experience with BPCI implementation, we reviewed a number of narrow episode definitions for LEJR episodes that were recommended by BPCI participants and other interested parties during the design phase for this project. We concluded that these narrow definitions commonly exclude many services that may be linked to the LEJR, as LEJR beneficiaries, on average, are at higher risk for more clinical problems than Medicare beneficiaries who have not recently undergone such procedures.

Therefore, we proposed that all CJR episodes, beginning with the admission for the anchor hospitalization under MS–DRG 469 or 470 through the end of the proposed episode, include all items and services paid under Medicare Part A or Part B with the exception of certain exclusions that would be excluded because they are unrelated to the episode. The items and services ultimately included in the episode after the exclusions are applied are called related items and services. As discussed in sections III.C.4. and III.C.6. of this final rule, Medicare spending for related items and services would be included in the historical data used to set target prices, as well as in the calculation of actual episode spending that would be compared against the target price to assess the performance of participant hospitals. In contrast, Medicare spending for unrelated items and services (excluded from the episode definition) would not be included in the historical data used to set target prices or in the calculation of actual episode spending.

We proposed that related items and services included in CJR episodes would be the following items and services paid under Medicare Part A or Part B, after the exclusions are applied:

- Physicians' services.
- Inpatient hospital services (including readmissions), with certain exceptions discussed later in this section.
- Inpatient psychiatric facility (IPF) services.
- Long Term Care Hospital (LTCH) services.
- IRF services.
- SNF services.
- HHA services.
- Hospital outpatient services.
- Independent outpatient therapy services.
- Clinical laboratory services.
- Durable medical equipment (DME).
- Part B drugs.
- Hospice.

We noted that under our proposed definition of related services included in the episode, the episode could include certain per-member-per-month model payments, as discussed in section III.C.7.d. of this final rule.

We proposed to exclude from CJR drugs that are paid outside of the MS–DRG, specifically hemophilia clotting factors (§ 412.115), identified through HCPCS code, diagnosis code, and revenue center on IPPS claims. Hemophilia clotting factors, in contrast to other drugs that are administered during an inpatient hospitalization and paid through the MS–DRG, are paid separately by Medicare in recognition that clotting factors are costly and essential to appropriate care for certain beneficiaries. Thus, in the proposed rule we stated our belief that there are no efficiencies to be gained in the variable use of these high cost drugs when particular beneficiaries receive LEJR procedures who have significantly different medical needs for clotting factors under an episode payment model, so we proposed to exclude these high cost drugs from the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price. Similarly, we proposed to exclude IPPS new technology add-on payments for drugs, technologies, and services from CJR episodes, excluding them from both the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price. This proposal would apply to both the anchor hospitalization

and any related readmissions during the episode. New technology add-on payments are made separately and in addition to the MS–DRG payment under the IPPS for specific new drugs, technologies, and services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Medicare pays a marginal cost factor of 50 percent for the costs to hospitals of the new drugs, technologies, or services. We did not believe it would be appropriate for the CJR model to potentially hamper beneficiaries' access to new technologies that are receiving new technology add-on payments or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward actual episode expenditures. In addition, because new drugs, technologies, or services approved for the add-on payments vary unpredictably over time in their application to specific clinical conditions, in the proposed rule we stated our belief that we should exclude IPPS new technology add-on payments from CJR episodes.

We followed a number of general principles in determining other proposed excluded services from the CJR episodes in order to promote coordinated, high-quality, patient-centered care. Based on the broad nature of these episodes, we proposed to identify excluded (unrelated) services rather than included (related) services based on the rationale that all Part A and Part B services furnished during the episode are related to the episode, unless they are unrelated based on clinical justification as described in more detail later in this section. In developing our proposals for exclusions for this model, we stated our belief that no Part A services, other than certain excluded hospital readmissions during the episode as described in this section, furnished post-hospital discharge during the episode should be excluded, as post-hospital discharge Part A services are typically intended to be comprehensive in nature. We also stated our belief that no claims for services with diagnosis codes that are directly related to the LEJR procedure itself (for example, loosening of the joint prosthesis) based on clinical judgment, and taking into consideration coding guidelines, should be excluded. Furthermore, we stated our belief that no claims for diagnoses that are related to the quality and safety of care furnished during the episode, especially the anchor hospitalization under MS–DRG 469 or 470, should be excluded, such as direct complications of post-surgical care during the anchor hospitalization. Examples of diagnoses that would not be excluded on this basis include surgical site infection and venous thromboembolism. Finally, in the proposed rule we stated our belief that no claims for services for diagnoses that are related to preexisting chronic conditions such as diabetes, which may be affected by care furnished during the episode, should be excluded. However, severe exacerbations of chronic conditions (for example, some surgical readmissions) that are unlikely to be affected by care furnished during the episode should be excluded; thus, when a beneficiary is admitted to the hospital during the episode for these circumstances, we would not consider it to be a related readmission for purposes of CJR. We also stated our belief that services for clinical conditions that represent acute clinical conditions not arising from an existing chronic clinical condition or complication of LEJR surgery occurring during an episode of care, which would not be covered by the previous principles about included services, should be excluded.

To operationalize these principles for CJR, we proposed to exclude unrelated inpatient hospital admissions during the episode by identifying MS–DRGs for exclusion. We proposed to exclude unrelated Part B services based on the ICD–9–CM diagnosis code (or their International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) equivalents when ICD–10–CM codes are implemented) that is the principal diagnosis code reported on claims for services furnished during the episode. More specifically, we proposed to exclude specific inpatient hospital admissions and services consistent with the LEJR episode definition (also triggered by MS–DRGs 469 and 470) that is currently used in BPCI Model 2. We note that the list of exclusions was initially developed over 2 years ago for BPCI through a collaborative effort of CMS staff, including physicians from medical and surgical specialties, coding experts, claims processing experts, and health services researchers. The list has been shared with thousands of entities and individuals participating in one or more phases of BPCI, and has undergone refinement over that time in response to stakeholder input about specific diagnoses or MS–DRGs for exclusion, resulting in only minimal changes over the last 2 years. Thus, the BPCI list of exclusions for LEJR procedures has been vetted broadly in the health care community; refined based on input from a wide variety of providers, researchers and other stakeholders; and successfully operationalized in the BPCI models. We proposed its use in CJR based on our confidence related to our several of years of experience that this definition is reasonable and workable for LEJR episodes, for both providers and CMS.

With respect to the proposed inpatient hospital admission exclusions for this model, we proposed that all medical MS–DRGs for readmissions be included in CJR episodes as related services, with the exception of oncology and trauma medical MS–DRGs. We proposed that admissions for oncology and trauma medical MS–DRGs be excluded from CJR episodes. Readmissions for medical MS–DRGs are generally linked to the hospitalization for the LEJR procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care. We refer readers to section III.D. of this final rule for background and discussion of the complication rate measure proposed for CJR that includes common medical complications resulting from the previously stated circumstances following LEJR procedures and that may result in related hospital readmissions. For readmissions for medical MS–DRGs, the selection of the primary diagnosis code is not clear-cut, so in the proposed rule we stated our belief that all should be included because providers should focus on comprehensive care for beneficiaries during episodes. We proposed to include all disease-related surgical MS–DRGs for readmissions, such as hip/knee revision, in CJR episodes. We also proposed to include readmissions for all body system-related surgical MS–DRGs as they are generally related to complications of the LEJR procedures. An example of a readmission of this type would be for an inferior vena cava filter placement for treatment of thromboembolic complications of the LEJR. We proposed to exclude hospital admissions for chronic disease surgical MS–DRGs, such as prostatectomy (removal of the prostate gland), as they are unrelated to the clinical condition that led to the LEJR and they would not have been precipitated by the LEJR. Finally, we proposed that hospital admissions for acute disease surgical MS–DRGs, such as appendectomy, be excluded because they are highly unlikely to be related to, or precipitated by, LEJR procedures and would not be affected by LEJR episode care redesign.

With respect to the LEJR proposed diagnosis code exclusions for Part B services for this model, we proposed that ICD–9–CM codes be excluded or included as a category and as identified by code ranges. We proposed that disease-related diagnoses, such as osteoarthritis of the hip or knee, are included. We also proposed that body system-related diagnoses are included because they relate to complications that may arise from interactions with the health care system. An example of this would be pressure pre-ulcer skin changes. Additionally, we proposed that all common symptom diagnoses are included because providers have significant discretion to select these as principal diagnosis codes. We proposed that acute disease diagnoses, such as severe head injury, are excluded. Finally, we proposed that chronic disease diagnoses be included or excluded based on specific clinical and coding judgment as described previously with respect to the original development of the exclusions for LEJR episodes under BPCI, taking into consideration whether the condition was likely to have been affected by the LEJR procedure and recovery period and whether substantial services were likely to have been provided for the chronic condition during the episode. Thus, chronic kidney disease and cirrhosis would be included in the episode, but glaucoma and chemotherapy would be excluded.

Proposed exclusions from CJR episodes were based on care for unrelated clinical conditions represented by MS–DRGs for readmissions during the episode and ICD–9 CM codes for Part B services furnished during the episode after discharge from the anchor hospitalization. The complete lists of proposed excluded MS–DRGs for readmissions and proposed excluded ICD–9–CM codes for Part B services are posted on the CMS Web site at *http://innovation.cms.gov/initiatives/cjr/*.

In the proposed rule, we noted that as CMS moves to implement ICD–10–CM we would make the CJR exclusions that would map to the final ICD–9–CM exclusions for CJR available in the ICD–10–CM format as well. We proposed that all Part A and B-covered items and services that would not be excluded based on the exclusions list are included in the episode. Furthermore, we proposed to update the exclusions list without rulemaking on an annual basis, at a minimum, to reflect annual changes to ICD–CM coding and annual changes to the MS–DRGs under the IPPS, as well as to address any other issues that are brought to our attention by the public throughout the course of the model test.

We would first develop potential exclusions list revisions of MS–DRGs for readmissions and ICD–9–CM (or ICD–10–CM, as applicable) diagnosis codes for Part B services based on our assessment against the following standards:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We proposed to post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input.

We sought comment on our proposals for identifying excluded readmissions and Part B-covered items and services, as well as our proposed process for updating the exclusions list.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters recommended that CMS clarify the proposal that named ''independent outpatient therapy services'' in the episode definition list of related Part A and Part B services included in the episode. The commenters pointed out that while this list specified ''independent outpatient therapy services,'' which would appear to only represent services furnished by therapists in private practices included in CMS data under certain supplier specialty codes, the commenters believe that CMS should refer to the services as outpatient therapy services in order to include all outpatient physical therapy, occupational therapy, and speech-language pathology therapy services in the definition of related Part A and Part B services included in the episode. The commenters noted that in the proposed rule discussion of CJR collaborators CMS referred to financial arrangements with outpatient therapy providers, a category of providers that was not defined in the proposed rule and has not otherwise been previously defined in the Medicare program. Therefore, the commenters recommended that CMS define outpatient therapy providers in regulation in the CJR final rule as a physician, supplier, or provider furnishing outpatient physician therapy services, outpatient occupational therapy services, or outpatient speech-language pathology services. The commenters suggested that CMS should then clarify that services furnished by these outpatient therapy providers (outpatient therapy services) would be included in the episode definition, thereby including these payments in the CJR historical episode data used to set target prices and in the calculation of actual episode spending that would be compared against the target price.

*Response:* We agree with the commenters' suggestion that we define outpatient therapy providers in regulation to ensure consistent and accurate reference to certain providers and services under the CJR model, and that we should include services furnished by outpatient therapy providers as related services in the CJR model after the exclusions are applied. Therefore, we are adding the following new definition to § 510.2: *Provider of outpatient therapy services* means a provider or supplier furnishing—(1) Outpatient physical therapy services as defined in 410.60 of this chapter, or (2) outpatient occupational therapy services as defined in 410.59 of this chapter, or (3) outpatient speech-language pathology services as defined in 410.62 of this chapter. We are also revising § 510.200(b)(10) to remove the word ''independent'' preceding outpatient therapy services.

*Comment:* Several commenters recommended that CMS add to the list of related services included in CJR model episodes drugs covered under Medicare Part D. The commenters asserted that Part D-covered drugs make important contributions to beneficiary health, especially for beneficiaries with chronic medical conditions and, therefore, should be included in a broadly defined episode payment model such as the CJR model to provide opportunities for improved quality and efficiency of care for beneficiaries.

*Response:* We appreciate the interest expressed by the commenters in including drugs covered under Part D in the LEJR episode definition used for the CJR model. However, while we agree with the commenters that the appropriate use of Part D-covered drugs can play an important role in improving a beneficiary's health, we will not be expanding our list of Part A and Part B items and services related to the episode to add Part D-covered drugs. We proposed to require all beneficiaries included in the CJR model to have both Part A and Part B coverage throughout the duration of the episode in order to ensure we had comprehensive episode payment data to calculate actual episode spending to be compared against the target price. However, enrollment in Part D is voluntary and a substantial percentage of Medicare beneficiaries do not have Part D coverage, so we would lack comprehensive payment information for all beneficiaries in the model in order to determine an episode target price and calculate actual episode spending. In addition, beneficiary-specific information about Part D drug spending that could be attributed to episodes would not be available in a timeframe consistent with the time periods for claims used to set target prices and the timeline for reconciliation where actual episode spending is aggregated and compared against the target price. Finally, given that the CJR model is testing LEJR episodes, we believe there is limited opportunity to shift spending from Part B to Part D to reduce actual episode spending, even though we have not included Part D payments in the episode definition. Most beneficiaries with chronic conditions would be taking similar drugs before and during the episode, and, other than pain medications, Part D-covered drugs are not commonly used to manage the direct post-surgical and PAC rehabilitation needs of most LEJR beneficiaries, who rarely experience significant complications from the surgery. Therefore, we are finalizing our proposal to not include all Part D-covered drugs from the list of related items and services included in CJR episodes.

*Comment:* Several commenters recommended that CMS exclude Inpatient Psychiatric Facility (IPF) services from CJR episodes because they would be unlikely to be related to the LEJR procedure. The commenters suggested that the services are always medically necessary with no opportunities for efficiency and would be more likely to be associated with injury that led to the need for LEJR procedure, rather than related to the surgical procedure or recovery. Several commenters stated that CMS should exclude these services from the episode definition because they were excluded under LEJR episodes in BPCI. Another commenter suggested that CMS exclude IPF services furnished more than 14 days after surgery because after than point, the commenter believes these services would be unlikely to be related to the surgery or recovery.

*Response:* We are clarifying that under BPCI, IPF services furnished following discharge from the LEJR episode anchor hospitalization but during the episode are included in the LEJR episode definition, unless they fall into one of the excluded MS–DRGs. Thus, we include inpatient psychiatric services whether paid under the IPPS or the IPF PPS in LEJR episodes under BPCI according to the same policy that would exclude readmissions paid under either payment system based on the same exclusion list. We see no reason under the CJR model not to apply the standard we proposed to define related and unrelated Part A and Part B services with respect to CJR episodes. Therefore, we believe the list of excluded MS–DRGs identifies those IPF admissions during the episode that would be clinically unrelated to the LEJR episode so we exclude them from the episode definition, whereas IPF services any time during a CJR episode that result in discharge from an MS–DRG that is not excluded would be related and included in the CJR model episode definition. We disagree with the commenter that all IPF services furnished more than 14 days after surgery are unlikely to be related to the LEJR procedure or complications of the procedure or to a chronic condition that must be managed differently as a result of the procedure. Regardless of the time IPF services are furnished following discharge from the anchor hospitalization, we believe the MS–DRG exclusions identify those circumstances when IPF services are unrelated to the CJR model episode. Therefore, consistent with the BPCI policy, we are finalizing our proposal to include IPF services in the CJR model episode definition when they are assigned to an MS–DRG that is not excluded from episode definition.

*Comment:* Several commenters commended CMS for proposing to include hospice services in the episode definition for the CJR model, which provides recognition of hospice services as an essential element of the health care continuum. They stated that they looked forward to CMS sharing data resulting from the model that provides insight into the impact of incorporating hospice as part of a bundled care model and coordinated approach to post-hospital care. However, the commenters asserted that generally hospice services would be unrelated to the LEJR episode because they would most commonly address a serious and unanticipated complication of surgery or the hospitalization, discovery during or immediately after the surgery of a previously undetected terminal prognosis, or an unrelated accident following the procedure. While acknowledging that some hospice services would be related to the LEJR episode under uncommon circumstances, the commenters encouraged CMS to include in the final rule the process that would be used to identify included and excluded hospice services from CJR episodes. The commenters urged CMS to further describe its rationale for including hospice services in the episode definition, and supply data that relates to hospice services and the CJR model. Finally the commenters recommended that CMS establish a data acquisition system on hospice use in the final model. Some commenters expressed confusion about CMS' proposal to include hospice services in the episode definition and inquired about whether CMS intended to include all hospice services or to exclude certain hospice services as unrelated to the LEJR episode according to the beneficiary's diagnosis.

A number of other commenters recommended that CMS exclude all hospice services from the CJR episode definition, except for the post-episode spending calculation that analyzes all Part A and Part B spending for model beneficiaries, both for consistency with BPCI and to ensure no incentives for underutilization of the hospice benefit were created by the CJR model. The commenters asserted that all hospice services were unrelated to the LEJR episode, and encouraged CMS to exclude hospice services in order to ensure timely access to hospice for CJR model beneficiaries.

*Response:* We appreciate the interest of the commenters in ensuring continuing beneficiary access to hospice services under the CJR model. We note that while we exclude all hospice services under BPCI, our proposal for the CJR model would exclude no hospice services. Specifically, we proposed no exclusions of Part A services furnished during the 90 day period after discharge from the anchor hospitalization other than certain hospital readmissions identified by excluded MS–DRGs. We understand that CJR model beneficiaries could receive hospice services during an episode under several different types of clinical circumstances. For example, the beneficiary could be enrolled in hospice prior to the LEJR episode, experience a pathologic hip fracture, and require THA to stabilize the beneficiary's hip. Alternatively, the beneficiary could have an LEJR procedure and enter into hospice at some point during the episode in the 90 days following discharge from the anchor hospitalization, either after experiencing a surgical complication leading to a terminal prognosis or based on a new diagnosis of a terminal stage of an illness. We note that given the pre-surgical screening that patients must undergo before an LEJR procedure, it would be rare for a new diagnosis that would render the patient terminally ill to occur within 3 months after the LEJR procedure that was not already identified during the pre-surgical screening process.

Medicare hospice care is palliative care for individuals with a prognosis of living 6 months or less if the terminal illness runs its normal course. As referenced in § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3 that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. When an individual is terminally ill, many health problems are brought on by underlying condition(s), as bodily systems are interdependent. Section 1861(dd)(1) of the Act establishes the services that are to be rendered by a Medicare certified hospice program and those services include: nursing care; physical therapy; occupational therapy; speech-language pathology therapy; medical social services; home health aide services (now called hospice aide services); physician services; homemaker services; medical supplies (including drugs and biologics); medical appliances; counseling services (including dietary counseling); short-term inpatient care (including both respite care and care necessary for pain control and acute or chronic symptom management) in a hospital, nursing facility, or hospice inpatient facility; continuous home care during periods of crisis and only as necessary to maintain the terminally ill individual at home; and any other item or service which is specified in the plan of care and for which payment may otherwise be made under Medicare, in accordance with Title XVIII of the Act. The services offered under the Medicare hospice benefit must be available, as needed, to beneficiaries 24 hours a day, 7 days a week (section 1861(dd)(2)(A)(i) of the Act).

The regulations at § 418.54(c) stipulate that the comprehensive hospice assessment must identify the patient's physical, psychosocial, emotional, and spiritual needs related to the terminal illness and related conditions, and address those needs in order to promote the hospice patient's well-being, comfort, and dignity. The comprehensive assessment must take into consideration the following factors: The nature and condition causing admission (including the presence or lack of objective data and subjective complaints); complications and risk factors that affect care planning; functional status; imminence of death; and severity of symptoms (§ 418.54(c)). Additionally, the hospice CoPs at § 418.56(c) require that the hospice must provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions and interventions to manage pain and symptoms. Therapy and interventions must be assessed and managed in terms of providing palliation and comfort without undue symptom burden for the hospice patient or family. In the December 16, 1983 Hospice final rule (48 FR 56010 through 56011), regarding what is related versus unrelated to the terminal illness, we stated: ''. . . we believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case–by-case basis. It is our general view that hospices are required to provide virtually all the care that is needed by terminally ill patients.''

Thus, hospice services furnished to CJR model beneficiaries should be included in the episode definition for the CJR model, regardless of the specific diagnosis of the beneficiary, because hospices are to provide virtually all care that is needed by terminally ill patients. If a CJR beneficiary was receiving hospice services during an episode, either because the beneficiary was enrolled in hospice prior to surgery and continued in hospice following surgery or the beneficiary enrolled in hospice following surgery that initiated the CJR model episode, we believe that hospice services would encompass care related to the LEJR episode and should, therefore, be included in the episode definition. As previously noted, given the comprehensive nature of the hospice benefit and the fact that body systems are interdependent at end of life, virtually all care needed by the terminally-ill individual would be related to the terminal prognosis and thus the responsibility of the hospice. As previously noted, hospices are required, per the Hospice CoPs at § 418.56(c), to provide all reasonable and necessary services for the palliation and management of the terminal illness, related conditions, and interventions to manage pain and symptoms. For patients that underwent LEJR procedures as part of the CJR model that have also elected the Medicare hospice benefit, hospice services would need to adapt and respond to the care needs of the CJR beneficiary following surgery. As in the case of other medically necessary services that would improve a beneficiary's quality of care and quality of life, we expect that CJR model beneficiaries will receive clinically appropriate referrals to hospice in a timely manner. Furthermore, we also believe hospice services could contribute to episode efficiency through improved comprehensive care coordination and management for CJR model beneficiaries that have a terminal prognosis. As previously stated, hospices are required to provide comprehensive care coordination and management per the hospice CoPs at 418.56. As discussed in sections III.F.3. and 5. of this final rule, we will be monitoring for access to care and delayed care and will take actions as described if problems are found. Therefore, we are finalizing our proposal to include hospice services in the CJR model episode definition.

With regard to the commenters' request for data regarding hospice use and the CJR model, we note that the evaluation approach described in IV.D. of this final rule will yield utilization information on CJR beneficiaries' episodes for specific types of providers and services. As discussed in section IV.E. of this final rule, we plan to evaluate the CJR model on an annual basis and release internal periodic summaries to offer useful insight, with

a final analysis after the end of the 5-year performance period. Finally, we plan to make available to participant hospitals upon their request periodic summary claims data reports or raw claims data, including payment information, using type of service categories that including hospice. We refer readers to section III.E.2. of this final rule for a more detailed discussion of the plans for sharing data under the CJR model.

*Comment:* Several commenters requested that CMS exclude prosthetic limbs, orthopedic braces, and customized durable medical equipment (DME) from the related services included in CJR model episodes. The commenters stated that these uncommonly furnished items were at risk of not being provided to CJR model beneficiaries, and provided historical example of access problems during implementation of the SNF PPS that eventually resulted in some HCPCS codes for these items being exempted from SNF consolidated billing. Another commenter requested clarification about included services with respect to the definition of DME. The commenter expressed its belief that there would be no need for verification by CMS or its contractors about coverage of DME as CMS would be making a single episode payment to hospitals. The commenter sought clarification that devices that would usually be paid for under the MS–DRG payment should be able to be used in the CJR beneficiary's home.

*Response:* While some commenters recommended that we exclude altogether certain prosthetics, braces, and customized DME from the episode definition under the CJR model, we believe that our Part B ICD–9–CM (or equivalent ICD–10–CM) diagnosis code exclusions will allow these items to be excluded when they are unrelated to the episode., both in determining historical CJR episode payments used to set the target price and in calculating actual episode spending during the model performance years Just as for other Part B services, when the primary ICD–9–CM (or equivalent ICD–10–CM) diagnosis code on the claim for the item is not excluded, the prosthetics, orthopedic braces, and customized DME will be included in the CJR episode. Because we will identify unrelated items when they are furnished, and the Medicare payment for those items will not be included in calculating the actual episode spending, we believe that CJR model beneficiaries will continue to have access to these items when they are furnished for unrelated diagnoses on the Part B ICD–10–CM diagnosis code exclusions list. With regard to the commenter who discussed a single payment by CMS to hospitals for the episode, we want to emphasize that this is a retrospective payment model and, thus, payments for all covered items and services will continue to be made under the usual Medicare program rules to all providers and suppliers furnishing services to CJR model beneficiaries, unless we have specifically waived certain Medicare program rules under the CJR model. We refer readers to section III.C.11. of this final rule for further discussion of waivers of Medicare program rules, but note that we have waived no existing requirements or conditions about DME. All existing program rules for coverage and payment of DME continue to apply. Therefore, we are finalizing our proposal to include DME in the CJR model episode definition, after application of the exclusions.

*Comment:* A number of commenters commended CMS on the proposal to exclude IPPS new technology add-on payments from the CJR model episode definition, as well as hemophilia clotting agents furnished to hospital inpatients. The commenters believe these policies will ensure access to these important treatments for CJR model beneficiaries who would benefit from them. Several commenters suggested that CMS also exclude from the CJR model episode definition OPPS transitional pass-through payments for devices, which are paid separately for a limited period of time based on their increased cost over existing technologies and evidence that they are a substantial clinical improvement, for consistency with CMS' proposed treatment of IPPS new technology add-on payments which accomplish the same objective for hospital inpatients. Other commenters recommended that CMS exclude other innovative technologies from the episode definition by establishing a review process to see if their cost should be removed from CJR episode spending to ensure that the financial incentives under the CJR episode payment model did not discourage appropriate use of new technologies for CJR model beneficiaries who would benefit from them. These commenters stated that such a policy would ensure that beneficiaries in the CJR model have access to beneficial new technologies that otherwise might be limited because of participant hospitals' concerns over providing items and services that would increase actual episode spending. A commenter, arguing in support of CMS' proposal to exclude IPPS new technology add-on payments from the episode definition, suggested that CMS analyze Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) data to see if customized joints correlated with HCAHPS scores under the model.

*Response:* We agree with the commenters that CJR model beneficiaries should have access to beneficial new technologies while they are in CJR episodes. We do not believe it would be appropriate for the CJR model to potentially hamper beneficiaries' access to new technologies that are receiving IPPS new technology add-on payments or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward actual episode expenditures. We also agree with the commenters' recommendation that we should exclude OPPS pass-through payments for medical devices from the episode definition for the same reasons we proposed to exclude IPPS new technology add-on payments. In both of these cases, through the established OPPS and IPPS review processes, we have determined that these technologies have a substantial cost but also lead to substantial clinical improvement for beneficiaries. Therefore, we are finalizing our proposal to exclude from the CJR episode definition IPPS new technology add-on payments and hemophilia clotting factors paid separately during an inpatient hospitalization. In addition, we are modifying our proposal and will exclude OPPS transitional pass-through payments for medical devices from the CJR model episode definition and price determinations.

We will not establish a new process to review innovative technologies and make individual determinations regarding their exclusion from the CJR model episode definition, as recommended by some commenters. Because the CJR model is a retrospective reconciliation model that pays all providers and suppliers under the regular Medicare program throughout the episode of care, we believe it is more appropriate to rely on the existing processes under the Medicare program to make determinations about separate payment for new technology items and services. If those existing processes identify new technologies that would qualify for add-on payments under the IPPS or transitional pass-through payment under the OPPS, we will exclude them from the CJR model episode definition to ensure that access to new technology items and services for beneficiaries is not influenced by their care being include in the CJR model. We note that the evaluation

approach for the model as discussed in section IV. of this final rule will analyze a variety of information about the model to draw conclusions about its effects on quality and cost but is not designed to examine patient experience as related to specific items or services furnished during the episode.

*Comment:* Most commenters expressed support for CMS' proposed episode definition that would exclude certain readmissions based on a list of MS–DRGs, as well as certain Part B services based on the principal diagnosis on the claim, consistent with the episode definition for LEJR episodes under BPCI that has been used for several years. The commenters acknowledged that most services would be included in the episode definition under the proposal, thus creating broadly defined episodes that should lead to comprehensive care for beneficiaries following LEJR procedures. A number of commenters characterized the proposed episode definition as clinically reasonable and agreed with the proposed lists of services that would be excluded. A commenter claimed that the proposed episode definition would encourage the integration of post-fracture care coordination, such as could be provided through a fracture liaison service, with acute care for CJR model beneficiaries with hip fractures, leading to improved outcomes. However, some commenters expressed general concern about CMS' proposal to hold participant hospitals financially accountable for these broadly defined episodes, especially as CMS did not propose to risk adjust target prices for the episodes to reflect beneficiaries' chronic conditions.

Several commenters suggested that CMS adopt an episode definition for the CJR model that is flexible and condition-specific. A commenter questioned the role of the beneficiary's health care provider in evaluating relatedness to the episode under the proposal and recommended that CMS permit the beneficiary's health care provider to make determinations of relatedness of services to the episode on a case-by case basis specific to a beneficiary's unique clinical condition. A few commenters suggested that CMS' proposed episode definition was more consistent with a total cost of care model by including beneficiaries with chronic conditions and excluding so few services. These commenters stated that if CMS finalizes such a broad definition, risk adjustment would be necessary in order to ensure fair payment to participant hospitals. Some commenters contended that CMS should include in the episode definition only services that are directly related to the procedure and complications for which the hospital could be held accountable. In the view of some commenters, CMS should exclude all chronic conditions from the episode definition, especially when the LEJR episode is unavoidable, such as in trauma cases. Examples provided by commenters of chronic conditions that should be excluded include diabetes and renal failure. Other commenters recommended that CMS only exclude care for unrelated chronic conditions and acute medical conditions such as urinary tract infection and dehydration occurring later than 30 days following discharge from the anchor hospitalization or otherwise shorten the episode duration of the model to 30 days. They claimed that holding the participant hospital accountable through the episode definition for chronic conditions two months after surgery is unfair. A commenter recommended that CMS include all readmissions for the first 30 days following discharge from the anchor hospitalization and thereafter only those hospital readmissions for the subsequent 60 days that are directly related to the LEJR procedures. Overall, a number of commenters expressed concern that unless CMS narrowed the proposed CJR model episode definition to exclude more services or diagnoses or shortened the episode duration, hospitals may be more cautious about treating patients with complex medical status, especially if CMS also does not risk adjust the target prices for the episode based on beneficiary characteristics and specific procedures.

A commenter stated that the proposed episode definition was not sufficiently broad for frail patients, especially those with multiple illnesses who may have had a hip fracture. The commenter contended that providers should be paid to provide comprehensive care and treat the whole person, who can have many different types of interrelated health care needs when he or she is acutely ill due to a hip fracture in the face of serious underlying chronic conditions. The commenter stated that the CJR model would contribute to the fracturing of comprehensive care for vulnerable beneficiaries by excluding some services from the episode definition, even if those services are for clinical conditions that appear to be clinically unrelated to the LEJR episode, and claimed that the solution to this challenge is moving people with complex medical needs into a patient-centered medical home or comprehensive ACO. The commenter stressed that any existing medical home or ACO arrangements that apply to CJR model beneficiaries should be respected by the participant hospital managing the CJR episode, so as to not disrupt or otherwise interfere with comprehensive care for beneficiaries with complex medical needs.

*Response:* We appreciate the support of many commenters for our proposed overall approach of identifying excluded services by MS–DRGs for hospital readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services for LEJR episodes that are broadly inclusive of related services. Because the methodology for setting episode prices as discussed in section III.C. of this final rule requires the construction of historical CJR episodes upon which to base target prices that are then compared with actual episode payment during each performance year of the model, we must use a standard episode definition for the CJR model to ensure comparability of services included in the episode in the historical CJR episode data and the model performance year. Thus, we are unable to adopt the suggestions of commenters that the CJR model episode definition be flexible or that health care providers make service-by-service determinations of relatedness for individual beneficiaries.

As discussed in the proposed rule and confirmed by the commenters, beneficiaries undergoing LEJR procedures have frequent comorbidities where their management may be affected by the surgery and post-operative recovery period. We do not believe it would be appropriate given the frequent comorbidities experienced by Medicare beneficiaries and the generally elective nature of LEJR to utilize a narrow episode definition for CJR that includes only those services directly related to the LEJR procedure or the quality or safety of the LEJR care, as we are interested in testing inclusive episodes to incentivize comprehensive, coordinated patient-centered care for the beneficiary throughout the episode. The care for many chronic conditions and the development of acute medical conditions may be affected by the LEJR procedure or post-surgical care throughout the post-surgical recovery period that extends significantly beyond 30 days following hospital discharge, a point in time where beneficiaries are usually still receiving PAC services, often including SNF services, and have not returned to their level of presurgical function. Therefore, we do not believe it would be appropriate to define services for chronic conditions and acute medical conditions as related to the CJR

model episode for 30 days post-discharge from the anchor hospitalization, and unrelated for the remaining 60 days in the episode. We believe that care for chronic medical conditions affected by the LEJR procedure or post-surgical care is related to the episode for the full episode duration because the care for these conditions is likely to be affected by the procedure and associated recovery for 90 days post-hospital discharge or even longer as the beneficiary recovers function over the course of the episode and returns to the community. We note that we have finalized several waivers of Medicare program rules as discussed in section III.C.11. of this final rule specifically to assist participant hospitals in efficient and effective care coordination and care management for CJR beneficiaries with significant, ongoing health needs, including chronic medical conditions whose care may be affected by the LEJR procedure and post-surgical recovery. Thus, we will exclude only those Medicare Part A and B-covered items and services furnished during the episode that are unrelated to LEJR procedures based on clinical justification, and the exclusions will apply throughout the episode duration. Finally, we believe that the payment policies of the model as described in sections III.C.3.c. and III.C.8. of this final rule to adjust pricing for high payment episodes and to provide stop-loss limits provide sufficient protections for participant hospitals from excessive financial responsibility for high payment cases that may result from the broad episode definition adopted for the model. We expect that participant hospitals, with responsibility for the quality and cost performance of CJR model episodes, will work closely with all providers, suppliers, and organizations engaged in the care of model beneficiaries, in order to ensure that efficient, coordinated care is furnished to the beneficiary.

We appreciate the concerns expressed by commenters about holding participant hospitals financially responsible for broad LEJR episodes extending 90 days post-discharge from the anchor hospitalization. We note that we are finalizing 90 days post-discharge from the anchor hospitalization as we proposed for the reasons discussed later in this section. Additionally, we refer readers to section III.C.4.b. of this final rule for the final policy that will risk stratify the target prices based on the presence or absence of a hip fracture for CJR model beneficiaries. We believe that this risk stratification policy addresses the commenters' concerns that beneficiaries with chronic conditions are likely to need more costly care throughout the CJR model episode that would have been inadequately paid under our proposal because these beneficiaries are those most likely to be present in the population receiving LEJR procedures emergently due to a hip fracture. Beneficiaries with chronic conditions are more likely to initiate CJR episodes due to hip fracture than beneficiaries without chronic condition who more likely undergo elective THA or TKA, so the typically higher historical spending for chronically ill beneficiaries will be reflected in the historical CJR episodes used to risk stratify target prices for hip fracture patients. In contrast, beneficiaries undergoing elective THA or TKA are less likely to have chronic conditions, so their typically lower historical spending will be reflected in the historical CJR episodes used to risk stratify target prices for LEJR patients without hip fracture. Thus, risk stratification of target prices based on a beneficiary's hip fracture status should account for patient-specific expenditure variation both directly resulting from more intense care due to the hip fracture itself, as well as indirectly resulting from the higher prevalence of chronic conditions that must be treated and managed in beneficiaries with hip fracture. We also believe that risk stratification based on a model beneficiary's hip fracture status will help to ensure that participant hospitals continue to treat these medically complex patients because target prices for these episodes will reflect the more costly care that these beneficiaries are likely to require based on historical experience.

Additionally, while we agree with the commenter that the ongoing and acute health care needs of medically complex beneficiaries may be addressed through a patient-centered medical home or ACO, many of these vulnerable beneficiaries currently are not included in such models or programs. In the case of other beneficiaries who are included in medical home or ACO models or programs, they may have specific, new care management needs arising from an LEJR procedure that may be best managed by the participant hospital that has substantial expertise in coordinating and managing care throughout LEJR episodes because of the hospital's participation in the CJR model, while the ACO or patient-centered medical home may have less specific expertise in managing beneficiaries recovering from major orthopedic surgery. We expect that participant hospitals, accountable for LEJR episode quality and cost performance under this model, will work closely with all providers and other organizations with which a model beneficiary has established relationships, toward the mutual goal of high quality, well-coordinated care that maximizes the rate of a beneficiary's return of function following surgery.

We are finalizing our proposal to include all Medicare Part A and B items and services in the CJR model episode definition, except for excluded services identified by the CJR model exclusions list, with modification to additionally exclude OPPS transitional pass-through payments for devices.

*Comment:* Many commenters expressed support for CMS' proposed approach to identifying excluded services by MS–DRGs for readmissions and ICD–9–CM diagnosis codes on Part B claims. Some commenters suggested that CMS consider additional coding sources beyond ICD–9–CM diagnosis codes to identify exclusions by adding ICD–9–CM procedure codes and HCPCS and/or CPT codes to the list of Part B exclusions.

*Response:* We appreciate the commenters' support for our proposal. We note that we have successfully used our current approach to identify excluded services for 48 clinical episodes under BPCI Models 2, 3, and 4 for several years. We will consider whether supplementing our current approach to identifying excluded services with additional coding strategies could help us more accurately identify unrelated services as we review future stakeholder input about the CJR model episode definition. We would need to also take into consideration the current coding requirements for different Part A and Part B services in assessing the potential benefit of supplementing our existing approaches to identifying excluded services. We would address any changes to the current CJR model approach to identifying excluded services through rulemaking. Therefore, we are finalizing our proposal to identify CJR model excluded services by MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services.

*Comment:* A number of commenters provided their perspective on certain specific proposed related services and exclusion. Several commenters expressed support for CMS' proposal to exclude readmissions for trauma medical and oncology MS–DRGs from the CJR episode definition. The commenters agreed with CMS that readmissions during LEJR episodes for

the clinical conditions that would result in discharge from trauma medical or oncology MS–DRGs would be clinically unrelated to the LEJR episode. A commenter recommended that CMS exclude rheumatoid arthritis care from the LEJR episode definition. While the commenter pointed out that rheumatoid arthritis can result in the need for LEJR procedures, the commenter observed that including treatment for rheumatoid arthritis in the episode would result in the accompanying high payments for this care being included in actual episode spending. The commenter stated that the high costs of treatment could either affect a beneficiary's treatment for rheumatoid arthritis during the CJR model episode or reduce the beneficiary's access to a medically necessary joint replacement. Several commenters recommended that CMS exclude services for which beneficiary claims data are not made available, specifically those subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 Code of Federal Regulations (CFR) part 2). Other commenters suggested that CMS exclude elective surgery during the CJR model episode, providing examples of cataract surgery, hernia repair, gallbladder procedures, and transurethral resection of the prostate. A commenter requested that CMS add the ICD–9–CM procedure code for chemotherapy administration to the Part B exclusions list, because CMS proposed to consider chemotherapy to be unrelated and, therefore, excluded from the CJR episode definition.

Several commenters requested further justification of CMS's proposals to include all body system-related surgical MS–DRGs and medical MS–DRGs except oncology and trauma medical MS–DRGs in the CJR episode definition. Several commenters requested further rationale for CMS' proposal to include all PAC services in the episode following an excluded readmission. Another commenter requested clarification on the inclusion of communication, cognitive, and swallowing-related diagnoses in the LEJR episode and CMS' intent in bundling services the commenter believes to be unrelated. The commenter also requested information about how providers could submit clinical justification when an exclusion of therapy services from the CJR model episode is needed. Finally, several commenters expressed support for excluding patients from the model with acute disease diagnoses such as head injury, based on their conclusion that CMS proposed to exclude these beneficiaries due to CMS' proposed exclusion of Part B claims reporting acute disease diagnoses, such as severe head injury.

*Response:* We appreciate the specific requests by the commenters for clarification and modification of our proposed list of exclusions from the CJR model episode definition. We agree with the commenters who supported our proposal to exclude readmissions resulting in discharges from oncology and trauma medical MS–DRGs. While we believe that readmissions for medical MS–DRGs are generally linked to the hospitalization for the LEJR procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care, we agree with the commenters that hospitalizations resulting in discharge from oncology and trauma medical MS–DRGs are not related to the hospitalization for the LEJR procedure.

We do not believe that Part B claims including ICD–9–CM diagnosis codes for rheumatoid arthritis should be excluded from CJR model episodes. This chronic condition is likely to be affected by care during the procedure and recovery period and, therefore, we would consider claims reporting these diagnoses codes to be related to the LEJR episode. With regard to the commenter's concerns about delays in timely treatment as a result of high treatment costs and reduced access to joint replacement procedures for beneficiaries with rheumatoid arthritis, we refer readers to sections III.F.3. and 5. of this final rule for discussion of our plans to monitor for access to care and delayed care due to the potential of the CJR model to direct patients away from more expensive services at the expense of outcomes and quality. We will also not exclude claims for substance abuse and mental health services that are not available in beneficiary claims data because these services are clinically related to LEJR episodes. Claims for substance abuse and mental health services include care for clinical conditions that are related to the CJR episode because these conditions may be affected by the LEJR procedure or post-surgical care. With regard to the commenters' requests that we exclude elective procedures such as cataract surgery, hernia repair, gallbladder procedures, and transurethral resection of the prostate from the CJR model episode definition, while we believe these procedures will be uncommon during the post-surgical recovery period for CJR model beneficiaries that extends 90 days following discharge from the anchor hospitalization, we will not exclude them as unrelated because all of the procedures may be related to care furnished during the post-surgical recovery period. Our exclusion methodology does not allow us to identify those procedures that are truly elective; that is, the condition was present and surgery was planned prior to the LEJR procedure and scheduled during the 90-cay post-hospital discharge period.

While we agree with the commenter that chemotherapy services should be excluded from the CJR model episode, our exclusion methodology for Part B services does not rely upon ICD–9–CM procedure codes but instead upon ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes reported on Part B claims. We note that the Part B payment systems, including those for physicians' services, Part B drugs, and institutional services, reject claims that do not report valid ICD–9–CM diagnosis codes. Therefore, we believe that our proposal to base Part B exclusions only on ICD–9 diagnosis codes and not additionally upon ICD–9 procedure codes should allow us to identify and exclude from the CJR episodes all Part B claims for chemotherapy administration services. Providers and suppliers do not report ICD–9–CM (or equivalent ICD–10–CM) procedure codes on Part B claims because they are paid for their chemotherapy and other services on the basis of the CPT or HCPCS codes that describe those services. However, these Part B claims must also include ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes. CMS requires ICD–9–CM (or equivalent ICD–10–CM) procedure codes to be reported only on Part A claims, which are excluded from the CJR model on the basis of readmission MS–DRG rather than ICD–9 (or equivalent ICD–10) codes, so adding ICD–9–CM (or equivalent ICD–10–CM) procedure codes to the Part B exclusions list is not necessary.

As we stated in the proposed rule, for readmissions to medical MS–DRGs the selection of the primary diagnosis code is not clear-cut so we believe they should all be included in the episode definition so that providers focus on comprehensive care to beneficiaries in episodes. We reiterate our belief that readmissions to medical MS–DRGs are generally linked to the hospitalization for the procedure as a complication of the illness that led to the surgery, a complication of treatment or interactions with the health care system, or a chronic illness that may have been affected by the course of care. Moreover,

we believe that all body-system related surgical MS–DRGs for readmissions are also related to the LEJR episode because these readmissions are generally related to complications of the LEJR procedure. Such surgeries result from the treatment of systemic conditions that arise from the LEJR procedure or its complications. Examples include placement of an inferior vena cava filer or a percutaneous coronary intervention for treatment of thromboembolic complications of the LEJR procedure.

We did not propose to exclude any PAC services in the 90-day post-hospital discharge period, even when those PAC services follow an excluded readmission. As Part A services are generally intended to be comprehensive in nature and because the beneficiary in a CJR model episode would still be in the post-operative recovery period following LEJR surgery, we believe any PAC services provided during the episode would be related to the LEJR procedure. Regardless of the reason for the hospitalization immediately preceding the initiation of PAC services, the PAC provider would need to address the beneficiary's post-surgical recovery from the LEJR procedure, even if the PAC services immediately followed an unrelated readmission to the hospital.

We did not propose to exclude claims for Part B services for communication, cognitive, or swallowing-related diagnoses from the CJR model episode definition because we believe these diagnoses are due either to chronic conditions whose care may be affected by the LEJR procedure or post-surgical care or to complications of the procedure, such as stroke, that result in these diagnoses. Therefore, we consider all Part B claims reporting these diagnoses in the principal diagnosis field to be related to the CJR episode. Providers are unable to submit clinical justification or other special requests for services to be designated as unrelated to the episode if one of these diagnoses is in the principal diagnosis field on claims. The CJR model is testing LEJR episode payment and we need consistency in the scope of the episode for the model. We will include all related Part A and Part B services as identified in this final rule in the calculation of episode target prices based on historical CJR episode data and in the calculation of actual episode spending for a model performance year.

Finally, in response to the commenters who supported the exclusion of beneficiaries with acute disease diagnoses, such as head injury, from the CJR model, we want to clarify that we did not propose to exclude these beneficiaries from the model. Instead, we proposed to exclude Part B claims reporting acute disease diagnoses from the episode because we consider these services to be unrelated under the episode definition. Therefore, we will not include claims for Part B services reporting excluded acute disease ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes in calculating target prices based on historical CJR episodes or in calculating actual episode spending that will be compared to the episode's target price in the CJR model.

We are finalizing our proposal to exclude the specific list of MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes that is posted on the CMS Web site at: *http://innovation.cms.gov/initiatives/cjr/.*

*Comment:* A commenter requested that CMS clarify how it will address hospital-acquired conditions that should never occur, when these conditions are part of CMS' Hospital-Acquired Condition Reduction Program and experienced by CJR model beneficiaries. The commenter explained that under current Medicare program policy, Medicare will not pay the higher MS–DRG arising from a specified list of non-reimbursable hospital-acquired conditions. The commenter pointed out that CMS proposed to not exclude claims for diagnoses related to the quality and safety of care furnished during the episode in the CJR model episode definition, but CMS' list of non-reimbursable hospital-acquired conditions includes surgical site infections after certain orthopedic procedures. In addition to clarifying how never events will be addressed in setting payments under the CJR model, the commenter recommended that CMS incorporate an analysis of never events and their incidence into the reconciliation process and review whether to expand the list of never events for elective surgeries.

Another commenter recommended that the CJR episode include a warranty for complications associated with surgery and other treatment, that is, if complications occur, they should be treated at no additional cost to the patient or Medicare.

*Response:* We appreciate the commenter's request for clarification about treatment of IPPS claims that include hospital-acquired conditions under the CJR model. Our model policy as discussed in section III.C.4. of this final rule bases the CJR target prices on historical CJR episodes that reflect discharge MS–DRGs and paid claim amounts for those beneficiaries who would have begun episodes by admission to an IPPS hospital that resulted in a discharge from MS–DRG 469 and 470. To the extent that Medicare does not pay the higher MS–DRG amount due to a hospital-acquired condition that was not present on admission, the lower payment for the hospitalization due to the hospital-acquired condition would be used in setting the episode target price for the MS–DRG that anchored the episode. This same would hold true for related readmissions during the episode. When calculating actual episode spending during a performance year, we would use, once again, the paid claim amount that, in the case of a hospital-acquired condition that was not present on admission, would be at the level of the lower paying MS–DRG for the anchor hospitalization or related readmission, as applicable. We further note that if a CJR beneficiary experiences a hospital-acquired condition that was not present on admission during an anchor hospitalization and has no other comorbid conditions other than the HAC that would result in assignment of MS–DRG 469, the beneficiary's episode would be considered an MS–DRG 470-anchored episode (initiated by the MS–DRG for LEJR procedures without complications). Therefore, the hospital-acquired condition penalty would not itself inflate the target price such that CMS would pay back the hospital-acquired condition penalty through a reconciliation payment.

Our proposal not to exclude claims for diagnoses related to the quality and safety of care during the episode is the basis for our excluded list of MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services and, therefore, this list would not apply to the anchor hospitalization itself where hospital-acquired conditions that were not present on admission could be reported.

As discussed in sections III.C.5. and 6. of this final rule, the model evaluation will examine changes in utilization, as well as outcomes and quality, in order to assess the impact of the CJR model on the aims of improved care quality and efficiency as well as well as reduced health care costs. We refer readers to section IV. of this final rule for further information on the planned evaluation. We have an ongoing process to review claims data regarding potential candidates for additions to the list of hospital-acquired conditions, so we do not believe there is a need to specifically identify CJR episodes for analysis because the IPPS claims included in CJR episodes would already be considered in the ongoing process used by CMS in the Hospital-Acquired Condition Reduction Program.

In response to the commenter who recommended for the CJR model that if complications due the LEJR procedure occur, they should be treated at no additional cost to the patient or Medicare, we note that because the CJR model uses a retrospective payment approach, we will rely on the existing Medicare program policies under the Hospital-Acquired Condition Reduction Program that define the specific circumstances in which Medicare will not make additional payment for a condition occurring after surgery. When these circumstances occur for CJR model beneficiaries in episodes, the existing Medicare program policies apply and Medicare would not provide additional payment. We do not believe it would be appropriate to establish policies specific to the CJR model regarding Medicare nonpayment for other complications, and we further note that some complications may not be preventable. The final pay-for-performance methodology for the CJR model as discussed in section III.C.5. of this final rule provides strong financial incentives for participant hospitals to coordinate and manage care to reduce complications, as the THA/TKA Complications measure (NQF #1550) contributes half of the available points for the hospital's composite quality score that determines the hospital's eligibility for reconciliation payments and quality incentive payments.

*Comment:* Several commenters opposed CMS' proposal to make changes to CJR model exclusions through an annual, at a minimum, update outside of rulemaking. Most commenters recommended that CMS update the exclusions annually through rulemaking, at least for routine annual updates. Other commenters stated that they did see value in CMS making possible additions and deletion to the exclusions list on a quarterly basis, especially early in the model. If following a quarterly process outside of rulemaking, these commenters urged CMS to seek stakeholder comment and input on candidate revisions through the CMS Web site and list serves to ensure broad input. The commenters encouraged CMS to adopt a transparent process for revisions to the episode definition in considering other exclusions. A number of commenters recommended that CMS explore other exclusions for the future, such as those inpatient hospital admissions or outpatient procedures planned for the beneficiary prior to the episode, ongoing care for patients' chronic conditions, and PAC following an excluded hospital readmission.

*Response:* We appreciate the interest of the commenters' in ensuring that any changes to the CJR model episode definition involve a transparent process with opportunity for broad stakeholder input. We continue to believe that updating the exclusions annually, at a minimum, outside of rulemaking, is most appropriate for this 5-year model, allowing for more frequent updates than through rulemaking as necessary to accommodate timely ICD–CM annual coding changes and the transition to ICD–10–CM and annual IPPS MS–DRG changes, as well as to address significant issues raised by participant hospitals and other stakeholders.

Commenters who supported an exclusions list update process outside of rulemaking did not suggest specific revisions to our proposed criteria for updating the exclusions, namely that:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

Thus, we continue to believe these criteria provide the appropriate clinical review framework for updates to the CJR model exclusions. Finally, we believe that our proposed process to post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input, is consistent with the recommendation of commenters that we use a transparent process reflective of robust opportunity for public input. Conducting this update process outside of rulemaking based on the criteria set forth in this final rule will allow us the greatest flexibility to update the exclusions as changes to the MS–DRGs and ICD diagnosis codes, upon which our exclusions rely, are released. This process will also allow us to respond quickly to any episode definition issues that arise during implementation of the model across the broad array of participant hospitals in the selected MSAs. We would widely publicize the opportunity for review and public input through the CMS Web site and listservs. We also note that any changes to our overall approach to identifying excluded services or to our criteria for evaluating services for exclusion would be addressed through rulemaking. Therefore, we are finalizing our proposal to update the exclusions list annually, at a minimum, using the process as described.

*Comment:* Several commenters referred to the impending change from ICD–9–CM to ICD–10–CM coding on claims and identified that this change would have implications for the Part B exclusions list. A commenters stated that CMS would need to define the excluded ICD–10–CM codes prior to implementation of the CJR model and recommended that CMS also provide the ICD–10–CM diagnosis code list that would identify included Part B services.

*Response:* We appreciate the commenters' interest in the list of CJR model exclusions that are identified based on ICD–10–CM codes. In the proposed rule, we stated that as we move to implement ICD–10–CM we would develop the CJR exclusions that would map to the final ICD–9–CM exclusions for CJR available in the ICD–10–CM format as well.

With ICD–10–CM implementation beginning in October 2015, we are making available the final CJR model Part B exclusions list in ICD–10–CM format as additional worksheet tabs to the final exclusions list posted on the CMS Web site at: *http://innovation.cms.gov/initiatives/cjr/.* This is the same list of exclusions that will be used for LEJR episodes under BPCI. This list will be applied to claims for services furnished on or after October 1, 2015 and that

report ICD–10–CM codes. For ease of understanding by the public, our objective was to present the ICD–10–CM excluded codes as ranges of excluded ICD–10–CM categories, just as we present the ICD–9–CM excluded codes as ICD–9–CM ranges.

To develop the ICD–10–CM exclusions list, we began with the list of final CJR ICD–9–CM code ranges. From that list of ranges, we generated an expanded list of all excluded ICD–9–CM codes. We then compared the list of excluded ICD–9–CM codes against both the ICD–9–CM-to-ICD–10–CM and ICD–10–CM-to-ICD–9–CM General Equivalence Mappings (GEMs) available at: *https://www.cms.gov/Medicare/Coding/ICD10/2015-ICD-10-CM-and-GEMs.html.* Comparing against both GEM files was necessary because there were matches in the ICD–9–CM-to-ICD–10–CM GEM that did not appear in the ICD–10–CM-to-ICD–9–CM GEM and vice versa. For example —

- In the ICD–9–CM-to-ICD–10–CM GEM file, ICD–9–CM code 85110 (Cortex (cerebral) contusion with open intracranial wound, unspecified state of consciousness) maps to ICD–10–CM code S0190XA (Unspecified open wound of unspecified part of head, initial encounter), but there is not a corresponding map from S019XA to 85110 in the ICD–10–CM-to-ICD–9–CM GEM.
- In the ICD–10–CM-to-ICD–9–CM GEM file, ICD–10–CM code A0101 (Typhoid meningitis) maps to ICD–9–CM code 020 (Typhoid), but there is not a corresponding map from 020 to A0101 in the ICD–9–CM to-ICD–10–CM GEM.

After compiling the results from both GEM files, we created a list of every billable ICD–10–CM code and whether each billable ICD–10–CM code matched to an excluded ICD–9–CM code. We then moved from the list of individual codes to a list of ICD–10–CM three-digit categories (for example, ICD–10–CM code A0101 (Typhoid meningitis) is in ICD–10–CM category A01 (Typhoid and paratyphoid fevers)) to present the final CJR exclusions. We excluded ICD–10–CM categories in which 100 percent of billable ICD–10–CM codes matched to an excluded ICD–9–CM code. There are 574 such categories, and we consider these CD–10–CM categories excluded based on a direct mapping from ICD–9–CM (see the ''Excluded Part B ICD10 Direct'' worksheet tab in the final exclusions list file). We did not exclude ICD–10–CM categories in which no billable ICD–10–CM codes matched to an excluded ICD–9–CM code. There are 1,258 categories, and we consider these categories not excluded based on a direct mapping from ICD–9–CM. For those 71 categories in which only some billable ICD–10–CM codes in the category matched to an excluded ICD–9–CM code after mapping, we excluded 48 ICD–10–CM categories where all of the ICD–10–CM codes in the category met one or more of our two final criteria for updating the excluded codes on the exclusions list as described previously in this section (see the ''Excluded Part B ICD10 Medical'' worksheet tab in the final exclusions list file). Specifically, the 48 ICD–10–CM categories that are excluded on this basis include ICD–10–CM codes that meet one or more of the following two criteria:

- Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode.
- Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We did not exclude the 23 other ICD–10–CM categories in which only some billable ICD–10–CM codes in the category matched to an excluded ICD–9–CM code after mapping because the ICD–10–CM codes in these categories met one or more of the following criteria:

- Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism).
- For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

When constructing prices for CJR, we will exclude Part B services from target prices and from performance year episodes based on the final excluded ICD–9–CM code ranges and final excluded ICD–10–CM code categories as appropriate, based on the applicable version of ICD diagnosis coding at the time the services was furnished.

In addition, we have addressed changes to the CJR model exclusion list that result from revisions for the FY 2016 IPPS. From FY 2015 to FY 2016, there were few changes to IPPS MS–DRGs that appear on the MS–DRG excluded readmissions list for the CJR model. Specifically, the FY 2016 IPPS update contains changes to existing MS–DRGs 237 and 238, Major Cardiovascular Procedures with MCC and without MCC, respectively, which are on the exclusions list for CJR episodes. For discharges after October 1, 2015, inpatient stays that previously would have been assigned to MS–DRG 237 or 238 will be assigned to one of the following MS–DRGs:

- 268 Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
- 269 Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
- 270 Other Major Cardiovascular Procedures with MCC.
- 271 Other Major Cardiovascular Procedures with CC.
- 272 Other Major Cardiovascular Procedures without CC/MCC.

We also note that the list of excluded readmissions posted with the proposed rule inadvertently omitted MS–DRGs 490 and 491, which were eliminated in the FY 2015 IPPS Final Rule and from which MS–DRGs 518, 519, and 520 were created in FY 2015. We are adding MS–DRGs 490 and 491 to the list of excluded readmissions posted with this final rule as we will exclude readmissions in MS–DRGs 490 and 491 for the purposes of calculating CJR target prices.

Additional information on the new MS–DRGs is provided in the FY 2016 IPPS final rule (80 FR 49371 through 49390, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html*). When constructing prices for CJR, we will exclude readmissions for MS–DRGs 237 and 238 in historical data. We will also exclude readmissions for MS–DRGs 268, 269, 270, 271, and 272 from performance year episodes.

*Summary of Final Decisions:* After consideration of the public comments we received, we are adding the following new definition for the CJR model: ''Provider of outpatient therapy services'' means a provider or supplier furnishing—(1) Outpatient physical therapy services as defined in § 410.60 of this chapter, or (2) outpatient occupational therapy services as defined in § 410.59 of this chapter, or (3) outpatient speech-language pathology

services as defined in § 410.62 of this chapter.

We are finalizing our proposal, with modification to remove the term ''independent'' preceding outpatient therapy services, that related items and services included in CJR episodes, defined by all of the clinical conditions requiring an admission to an IPPS hospital that results in a discharge from MS–DRG 469 or 470 would be the following items and services paid under Medicare Part A or Part B, after the final exclusions are applied:

- Physicians' services.
- Inpatient hospital services (including readmissions), with certain exceptions, as discussed later in this section.
- IPF services.
- LTCH services.
- IRF services.
- SNF services.
- HHA services.
- Hospital outpatient services.
- Outpatient therapy services.
- Clinical laboratory services.
- DME.
- Part B drugs.
- Hospice.

Medicare spending for related items and services will be included in the historical data used to set episode target prices, as well as in the calculation of actual episode spending that would be compared against the target price to assess the performance of participant hospitals. In contrast, Medicare spending for unrelated items and services (excluded from the episode definition) will not be included in the historical data used to set target prices or in the calculation of actual episode spending.

Additionally, we are finalizing our proposal to exclude inpatient hospital readmissions based on the list of excluded MS–DRGs and Part B services that report an excluded ICD–9–CM (or equivalent ICD–10–CM) diagnosis code as the principal diagnosis based on the list posted on the CMS Web site at: *http://innovation.cms.gov/initiatives/cjr/.* As we proposed, we will exclude IPPS new technology add-on payments for drugs, technology, and services and hemophilia clotting factors paid separately during an inpatient hospitalization from the CJR model episode definition. We are modifying our proposal and, under our final policy, we will also exclude OPPS transitional pass-through payments for devices. We are also finalizing our proposal to update the exclusions list without rulemaking on an annual basis, at a minimum, to reflect annual changes to ICD–CM coding and annual changes to the MS–DRGs under the IPPS, as well as to address any other issues that are brought to our attention by the public throughout the course of the model test.

We will first develop potential exclusions list revisions of MS–DRGs for readmissions and ICD–9–CM (or equivalent ICD–10–CM) diagnosis codes for Part B services based on our assessment against the following standards:

- We would not exclude any items or services that are—

++ Directly related to the LEJR procedure itself (such as loosening of the joint prosthesis) or the quality or safety of LEJR care (such as post-surgical wound infection or venous thromboembolism); and

++ For chronic conditions that may be affected by the LEJR procedure or post-surgical care (such as diabetes). By this we mean that where a beneficiary's underlying chronic condition would be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care must be managed differently as a result of the chronic condition, then those items and services would be related and would be included in the episode.

- We would exclude items and services for—

++ Chronic conditions that are generally not affected by the LEJR procedure or post-surgical care (such as removal of the prostate). By this we mean that where a beneficiary's underlying chronic condition would not be affected by the LEJR procedure, or where the beneficiary's LEJR or post-LEJR care need not be managed differently as a result of the chronic condition, then those items and services would not be related and would not be included in the episode; and

++ Acute clinical conditions not arising from existing episode-related chronic clinical conditions or complications of LEJR surgery from the episode (such as appendectomy).

We will post the potential revised exclusions, which could include additions to or deletions from the exclusions list, to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the exclusions list with posting to the CMS Web site of the final revised exclusions list after our consideration of the public input. Through the process for public input on potential revised exclusions and then posting of the final revised exclusions, we will also provide information to the public about when the revisions would take effect and to which episodes they would apply. These parameters could vary, depending on the relationship of exclusion list changes to annual ICD–CM or MS–DRG changes or to other issues brought to our attention by the public. While these revised exclusions may correspond to the time when we provide new target prices for a performance year, depending on the timing of when they would take effect and to which episodes they would apply, we would recalculate target prices as necessary.

The final definitions are set forth in § 510.2 which has been revised to remove proposed (b)(3) for inpatient hospital readmission services because hospital readmissions are already referenced in (b)(2). The remaining provisions under § 510.2(b) have been renumbered accordingly. The final policies for included services, excluded services, and updating the lists of excluded services are set forth in § 510.200(b), (d), and (e). We note that § 510.200(d)(3) has been renumbered to § 510.200(d)(4) and § 510.200(d)(3) added to state, ''Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter.'' In addition, § 510.200(b)(10) has been modified to read ''Outpatient therapy services.''

3. Duration of Episodes of Care

a. Beginning the Episode and Beneficiary Care Inclusion Criteria

While we proposed to identify LEJR episodes by an acute care hospitalization for MS–DRG 469 and 470, we recognize that the beneficiary's care for an underlying chronic condition, such as osteoarthritis, which ultimately leads to the surgical procedure, typically begins months to years prior to the surgical procedure. Because of the clinical variability leading up to the joint replacement surgery and the challenge of identifying unrelated services given the multiple chronic conditions experienced by many beneficiaries, we did not propose to begin the episode prior to the anchor hospitalization (that is, the admission that results in a discharge under MS–DRG 469 or 470). In the proposed rule, we stated our belief that the opportunities for care redesign and improved efficiency prior to the inpatient hospitalization are limited for an episode payment model of this type that focuses on a surgical procedure and the associated recovery once the decision to pursue surgery has been made, rather than an episode model that focuses on decision-making and management of a clinical condition itself (such as osteoarthritis).

We proposed to begin the episode with an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in

accordance with the methodology described. This proposal to begin the episode upon admission for the anchor hospitalization is consistent with LEJR episode initiation under Model 2 of BPCI. While we did not propose to begin the episode prior to the inpatient hospital admission, we noted that our proposed episode definition includes all services that are already included in the IPPS payment based on established Medicare policies, such as diagnostic services (including clinical diagnostic laboratory tests) and nondiagnostic outpatient services related to a beneficiary's hospital admission provided to a beneficiary by the admitting hospital, or by an entity wholly owned or wholly operated by the admitting hospital (or by another entity under arrangements with the admitting hospital), within 3 days prior to and including the date of the beneficiary's admission. For more information on the 3-Day Payment Window payment policies, see CMS Pub. 100–04, Chapter 3, section 40.3 and Chapter 4, section 10.12.

We proposed that the defined population of Medicare beneficiaries whose care will be included in CJR meet the following criteria upon admission to the anchor hospitalization. We noted that these criteria are also consistent with Model 2 of BPCI, as well as most other Innovation Center models that do not target a specific subpopulation of beneficiaries. We proposed that the LEJR episodes for all beneficiaries in the defined population will be included in CJR (although we proposed that certain episodes may be canceled for purposes of determining actual episode payments for reasons discussed later in this final rule), and we refer readers to section III.F.2. of this final rule for further discussion of beneficiary notification and a beneficiary's ongoing right under CJR to obtain health services from any individual or organization qualified to participate in the Medicare program.

- The beneficiary is enrolled in Medicare Part A and Part B throughout the duration of the episode.
- The beneficiary's eligibility for Medicare is not on the basis of End Stage Renal Disease (ESRD).
- The beneficiary must not be enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost-based health maintenance organizations).
- The beneficiary must not be covered under a United Mine Workers of America health plan, which provides healthcare benefits for retired mine workers.
- Medicare must be the primary payer.

Our proposal for inclusion of beneficiaries in CJR is as broad as feasible, representing all those LEJR episodes for which we believe we have comprehensive historical Medicare payment data that allow us to appropriately include Medicare payment for all related services during the episode in order to set appropriate episode target prices. For beneficiaries whose care we proposed to exclude from the model, we are unable to capture or appropriately attribute to the episode the related Medicare payments because of Medicare's payment methodology. For example, if a beneficiary is enrolled in a Medicare Advantage plan, Medicare makes capitated payments (and providers do not submit complete claims data to CMS), so we would not have a way to identify and attribute the portion of those payments related to an LEJR episode. More information on setting bundled payment target prices for episodes under CJR is available in section III.C.4.b. of this final rule. Including the broadest feasible array of Medicare beneficiaries' admissions in the model would provide CMS with the most robust information about the effects of this model on expenditures and quality for beneficiaries of the widest variety of ages and comorbidities, and allow the participant hospitals the greatest opportunity to benefit financially from systematic episode care redesign because most Medicare beneficiaries undergoing an LEJR procedure will be included in the model and, therefore, subject to the policies we proposed.

We sought comment on our proposal on when to begin the CJR episode, as well as to identify the care included for beneficiaries.

The following is a summary of the comments received and our responses.

*Comment:* Most commenters agreed that the episode should begin with the hospital admission for the LEJR procedure. Some of these commenters noted that it would not be appropriate to include the period prior to the hospital admission as it could include unrelated care and introduce variability.

Several orthopedic surgeons commented that physician treatment and care management begin prior to surgery, with the physician continuing to manage care during surgery, following surgery, and throughout the entire PAC period. These commenters were concerned that beginning the episode with the hospital admission would result in beneficiaries choosing and initiating care plans designed with their treating physicians and later, when hospitalized, the beneficiaries would receive conflicting care plans and, ultimately, experience adverse outcomes.

Many commenters recommended starting the episode earlier than the hospital admission. Some commenters recommended starting the episode once the decision to pursue surgery is made, and some recommended specific timeframes that ranged between four to eight weeks prior to the surgery. Some commenters provided examples of presurgical services that they have found improve patient outcome and satisfaction, improve care quality, and reduce costs, such as comprehensive patient evaluations to assess a beneficiary's overall condition and chronic comorbid conditions; pre-surgical counseling for non-medical pain management; home safety reviews; post-discharge planning; patient and caregiver education; weight loss programs; and physical therapy. Some commenters requested that CMS consider additional program rule waivers for the CJR model, beyond those specifically proposed, to facilitate the provision of various preoperative services and incentives that are not allowed or payable under current Medicare rules.

A few commenters were concerned that starting the episode with the hospital admission may lead to participants shifting costs to just prior to the start of the episode to receive payments for those services in addition to the bundle. To minimize gaming, they recommended starting the episode once the surgery has been elected and prior to the hospital admission, which is consistent with many private sector models.

*Response:* We appreciate the interest expressed by the commenters in starting comprehensive care coordination prior to the hospital admission, and we recognize that the beneficiary's care which ultimately leads to the LEJR surgery, including the physician-patient relationship, often begins long before the surgical procedure. We also appreciate concerns about providers unbundling services and shifting costs to just prior to the episode, between the time the surgery has been elected and the hospital admission. However, beginning the episode too far in advance of the LEJR surgery would make it difficult to avoid bundling unrelated items, and starting the episode prior to the hospital admission is more likely to encompass costs that vary widely among beneficiaries, which would make the episode more difficult to price appropriately.

We appreciate commenters' suggestions of pre-surgical services and

programs that could support the continuum of care for CJR beneficiaries. However, identifying a specific set of related presurgical services to include in the episode, as recommended by some commenters, would be of little value in the model because many of the services that are typically necessary or the standard of care prior to surgery are often included in the IPPS payment under the three day payment window payment policies and are therefore already included in the CJR episode. We note that some of the related services suggested by commenters that are not typically included in the three-day payment window are intended to more broadly manage the clinical condition(s) that may have led to the LEJR, and as discussed previously in this section, the CJR model is designed to focus on the surgical procedure and the associated recovery. We also note that some of these suggested services would be applicable to a subset of CJR beneficiaries and, therefore, do not present a significant opportunity for improving efficiency and redesigning care management for the typical beneficiary receiving an LEJR.

We believe that using the date of admission as the start of the episode is appropriate as hospitals are unlikely to shift related services earlier than when is clinically indicated. With respect to expanding the waivers to presurgical services that are not currently covered or payable, we have finalized several waivers of Medicare program rules as discussed in section III.C.11. of this final rule specifically to assist participant hospitals in efficient and effective care coordination and care management for CJR beneficiaries, and we do not believe it would be consistent with the model design or otherwise necessary for the model test to implement waivers for the preoperative period. While we appreciate commenters' interest in providing additional presurgical services that may enhance care coordination and care management, the waivers of Medicare program rules are only available if the beneficiary is in the episode at the time a service under the waiver is furnished. We believe that allowing waivers in the preoperative period prior to the anchor hospitalization, based on an expectation that a beneficiary will be in a CJR Model episode, would not be appropriate as there is no guarantee that the beneficiary will actually initiate a CJR Model episode and qualify for services furnished under a waiver.

For purposes of the CJR model, we continue to believe that beginning the episode with the anchor hospitalization is most appropriate due to the clinical variability leading up to the joint replacement surgery and the challenge of distinguishing between related and unrelated services. We also believe that beginning the episode with the anchor hospitalization, and not prior to admission, would be easier to administer and provide more consistent episodes for testing the CJR Model. Therefore, we are finalizing our proposal to begin the episode with admission to an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in accordance with the methodology described.

*Comment:* Commenters generally supported the proposed beneficiary inclusion criteria as reasonable and consistent with other programs. Some commenters suggested we exclude additional populations from CJR, namely beneficiaries with serious conditions or acute diseases, such as traumatic brain injury, spinal cord injuries, multiple-limb trauma, amputations, moderate to severe strokes, severe neuromuscular and musculoskeletal conditions, HIV infection, and cancer. A commenter recommended that we design a separate model to address the needs of patients with chronic conditions. A few commenters recommended excluding all patients on hospice.

Many commenters recommended that if we did not exclude high risk cases, we must develop more robust risk adjustment to account for socioeconomic, clinical, or other risk factors that are out of the hospital's control and impact patients' health and recovery. Some commenters were concerned that without accurate risk adjustment, hospitals will have an incentive to avoid higher-risk LEJR candidates. A commenter cited a study that found significant differences in Medicare spending per beneficiary during the 90-day episode based on various patient characteristics, such as type of LEJR surgery; emergency versus scheduled surgery; hip fractures versus degenerative conditions; patients age 85 or older; patients with multiple comorbidities, and patients who were dual eligible. The commenter asserted that robust risk adjustment based on the risk profile of each hospital's patients is essential for the CJR model because individual hospitals will not have enough enrollment to spread their risk. A few commenters recommended that at least the initial implementation of the Model should exclude vulnerable populations with complicated or intensive care needs until the CJR model demonstrates sufficient quality outcomes and has developed accurate risk adjustments and patient safeguards to ensure high-quality care for populations that the commenters believe could face serious care disadvantages in the CJR model.

*Response:* Many beneficiaries undergoing procedures that result in discharge from MS–DRG 469 and 470 have underlying conditions that may affect care throughout the episode or that may be influenced by the surgical procedure that initiates the episode. We believe it is important to include these beneficiaries in the model so that they can benefit from care coordination and management throughout the episode, and including the broadest feasible array of Medicare beneficiaries in the CJR model provides participant hospitals with greater incentive to redesign episode care. We also believe that patients in hospice would benefit from the improved comprehensive care coordination incentivized by the CJR model, and we refer readers to the related discussion in section III.B.2. of this final rule regarding our policy to include hospice claims in the episode.

We refer readers to section III.C.4.b. of this final rule for the final policy that will risk stratify the target prices based on the presence or absence of a hip fracture for CJR model beneficiaries. We believe that this risk stratification policy addresses many of the commenters' concerns that beneficiaries with serious conditions, acute diseases, and chronic conditions are likely to need more costly care throughout the CJR model episode that would have been inadequately paid under our proposal because these beneficiaries are those most likely to be present in the population receiving LEJR procedures emergently due to a hip fracture.

*Comment:* Several commenters recommended that CMS exclude beneficiaries who opted out of data sharing. These commenters asserted that it would be virtually impossible to manage risk and improve outcomes without claims data.

*Response:* As discussed in section III.E. of this final rule, we have decided not to finalize our proposal to allow beneficiaries the opportunity to decline having their data shared. We refer readers to section III.E. of this final rule for additional discussion of data sharing.

*Comment:* Some commenters suggested that CMS limit the CJR model to beneficiaries that live within a limited distance from participant hospitals so that the hospital would not be penalized for inadequately managing the PAC of medically complex patients from remote or distant locations.

*Response:* We expect that in some limited circumstances, participant

hospitals will have limited ability to coordinate care. However, following the care coordination that takes place in the hospital, we believe that much of the subsequent coordination for PAC can be accomplished through telecommunications that do not require the patient to remain within geographic proximity of the hospital. Moreover, the design of the model does not preclude hospitals from coordinating care with local providers outside of their immediate referral area. We also note that we have finalized several waivers of Medicare program rules, as discussed in section III.C.11. of this final rule, to facilitate efficient and effective care coordination for beneficiaries in remote or distant locations outside the immediate community. Therefore, we will not exclude beneficiaries who are referred to participant hospitals from other areas.

*Comment:* A commenter requested CMS to consider including beneficiaries enrolled in MA plans in the model as they are likely to be healthier and their inclusion will help hospitals maintain costs within their targets. The commenter recognizes that the CJR payment methodology makes it difficult to identify and attribute payment related to the LEJR episode. However, the commenter asserts that participant hospitals in states with a high percentage of beneficiaries enrolled in MA plans are more likely to care for CJR patients with a higher than average risk profile, which could make it more difficult for a hospital to maintain costs within the target rate.

*Response:* We appreciate the commenter's interest in increasing the population of beneficiaries included in the CJR model, and we recognize that participant hospitals with higher risk CJR beneficiaries may find it more challenging to maintain actual aggregate episode payments within their target price. However, as discussed previously in this section, Medicare makes capitated payments for beneficiaries enrolled in MA plans, and providers do not submit complete claims data to CMS. Therefore, we are finalizing our proposal not to include beneficiaries enrolled in MA plans because we are unable to capture or appropriately attribute to the episode the related Medicare payments.

*Comment:* A couple of commenters requested that CMS exclude episodes where the LEJR surgery was furnished either by an opt-out physician, because the principal procedure is not paid by Medicare, or by a non-participating physician who does not accept assignment. They requested that if such episodes are to be included, CMS should establish policies under which participant hospitals can provide reconciliation payments to and receive alignment payments from opt-out physicians as well as non-participating physicians.

*Response:* Consistent with the BPCI policy, we do not believe it would be appropriate to exclude beneficiaries from the CJR model if a physician who opted out of Medicare pursuant to § 405.420 or a non-participating physician performs the LEJR surgery during the anchor hospitalization. We would expect that beneficiaries undergoing LEJR procedures, regardless of the Medicare participation or opt-out status of the operating surgeon, would have similar needs for care coordination and management throughout the episode period that extends 90 days post-hospital discharge, and we see no reason that hospitals should not have the same quality and cost performance responsibility for these episodes. We note that less than 15 percent of episode spending, on average, would be expected to be paid for physicians' services, with more than 80 percent of the episode payment made for inpatient hospital and PAC services. Thus, for a beneficiary who otherwise meets the CJR model's inclusion criteria, a CJR model episode would begin at the time of the beneficiary's admission for the anchor hospitalization, regardless of whether an opt-out physician or non-participating physician performs the LEJR surgery during that stay.

We refer readers to section III.C.3. of this final rule for discussion of the effect on reconciliation payments on services furnished by non-participating and opt-out physicians and to section III.C.10.a. of this final rule for discussion of issues related to gainsharing payments and alignment payments.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our proposal to begin the episode with admission for an inpatient anchor hospitalization for MS–DRG 469 or MS–DRG 470 in accordance with the methodology described. We also are finalizing our proposal as to the criteria for beneficiary inclusion in the model as follows:

- The beneficiary is enrolled in Medicare Part A and Part B throughout the duration of the episode.
- The beneficiary's eligibility for Medicare is not on the basis of ESRD.
- The beneficiary must not be enrolled in any managed care plan (for example, Medicare Advantage, Health Care Prepayment Plans, cost based health maintenance organizations).
- The beneficiary must not be covered under a United Mine Workers of America health plan, which provides healthcare benefits for retired mine workers.
- Medicare must be the primary payer.

The final policies for beginning an episode are set forth in § 510.210(a). The final policies for beneficiary inclusion are set forth in § 510.205.

b. Middle of the Episode

We proposed that once the episode begins for a beneficiary whose care is included, the episode continues until the end as described in the next section of this final rule, unless the episode is canceled because the beneficiary no longer meets the same inclusion criteria proposed for the beginning of the episode at any point during the episode. When an episode is canceled, we proposed that the services furnished to beneficiaries prior to and following the episode cancellation will continue to be paid by Medicare as usual but we will not calculate actual episode spending that would otherwise under CJR be reconciled against the target price for the beneficiary's care (see section III.C.6. of the proposed rule). As discussed in section III.C.11.a. of the proposed rule, if the beneficiary is in the episode at the time the service under the waiver is furnished, the waiver is available, even if the episode is later canceled.

In the proposed rule, we stated our belief that it would be appropriate to cancel the episode when a beneficiary's status changes during the episode such that they no longer meet the criteria for inclusion because the episode target price reflects full payment for the episode, yet we would not have full Medicare episode payment data for the beneficiary to reconcile against the target price.

In addition, we proposed that the following circumstances would also cancel the episode:

- The beneficiary is readmitted to an acute care hospital during the episode and discharged under MS–DRG 469 or 470 (in this case, the first episode would be canceled and a new LEJR episode would begin for the beneficiary).
- The beneficiary dies during the anchor hospitalization.
- The beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3 or 4.

In the case of beneficiary death during the anchor hospitalization, we stated our belief that it would be appropriate to cancel the episode as there are limited efficiencies that could be expected during the anchor hospitalization itself. In the case of beneficiary readmission during the first

CJR episode for another LEJR (typically a planned staged second procedure), we stated our belief that it would not be appropriate to include two episodes in the model with some time periods overlapping, as that could result in attribution of the Medicare payment for 2 periods of PAC to a single procedure.

We sought comment on our proposals to cancel episodes once they have begun but prior to their end.

The following is a summary of the comments received and our responses.

*Comment:* Commenters were generally supportive of our proposals for canceling the episode, though many recommended additional circumstances for canceling the episode, such as adverse events which are beyond the hospital's control. Many commenters, including MedPAC, recommended that CMS cancel the episode if the beneficiary dies at any time during the episode, arguing that such cases could be extremely low or high cost and spending is, therefore, not typical. These commenters recommended that all episodes that end in patient death should be excluded from the calculations of the target price and reconciliation amounts, not just those episodes where patients die during the initial hospitalization as CMS proposed, as this type of episode of care could skew the data. Given that hospitals are held financially responsible for the entire 90-day episode, a few commenters suggested excluding all episodes with death for consistency and administrative simplicity. A commenter observed that a deceased beneficiary no longer meets all of the beneficiary inclusion criteria, and on that basis recommended that CMS cancel the episode when the patient dies. A commenter suggested also canceling episodes for any beneficiaries that die during the 30 day post-episode monitoring period. Some commenters suggested that other circumstances should cancel an episode, such as a beneficiary geographic move, change in beneficiary residence from a home to a facility, and loss of the beneficiary to follow up care.

*Response:* While beneficiary deaths during LEJR episodes are uncommon, we expect them to vary unpredictably across hospitals and, therefore, we agree that it would be appropriate to cancel episodes under these circumstances. We also agree that canceling all episodes during which a beneficiary dies is consistent with the otherwise applicable episode duration as the episode would not extend to 90 days hospital post-discharge. However, we would include episodes where the patient dies during the 30 days post-episode as this would not affect the variability of episode spending, and it would be appropriate to monitor for beneficiary death during the immediate post-episode period.

We expect some limited circumstances where participant hospitals will have limited ability to coordinate care. However, we believe that participant hospitals will be incentivized to seek creative solutions that do not rely on in-person services, and we are finalizing our proposal that all other beneficiary episodes would remain in the CJR model, regardless of where the beneficiary is located. Payment for beneficiaries in these circumstances will be reflected in the target prices based on historical utilization.

*Comment:* Commenters urged CMS to hold beneficiaries and providers financially harmless for care received as part of a CJR episode if the episode is later canceled. A few commenters supported the continued application of Medicare program waivers if an episode is canceled when a beneficiary's status changes, and a few commenters were unclear if waivers apply to beneficiaries who are retrospectively identified as ineligible for CJR program waivers due to changes in coverage status.

*Response:* As discussed previously in this section, we proposed that if the beneficiary is in the episode at the time the service under the program rule waiver is furnished, the waiver is available, even if the episode is later canceled. If the beneficiary is not in the episode at the time the service under the waiver is furnished, financial liability for these services would be determined in accordance with the policies outlined in the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 30. As we gain experience with CJR, we may revisit this issue in future rulemaking. We refer readers to section III.C.11. of this final rule for additional discussion and our finalized policy to apply waivers of programs rules if the beneficiary is in the episode at the time the service under the waiver is furnished, even if the episode is later canceled.

*Comment:* A commenter was concerned that initiation of a BPCI episode would cancel a CJR episode, when the CJR episode begins first. The commenter also requested clarification whether a BPCI episode for a different clinical condition, such as cardiac procedures, would cancel a CJR LEJR episode.

*Response:* We proposed and are finalizing our policy that a CJR episode would be canceled when a beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3, or 4. A CJR beneficiary initiating a different clinical episode under BPCI Models 1, 2, 3, or 4 would remain in a CJR episode. We refer readers to section III.C.7.b. of this final rule for additional discussion of CJR beneficiary overlap with BPCI episodes.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our proposal to cancel episodes once they have begun but prior to their end if the beneficiary no longer meets the same inclusion criteria proposed for the beginning of the episode at any point during the episode. We also are finalizing our proposal that the following circumstances would also cancel an episode:

- The beneficiary is readmitted to a participant hospital during the episode and discharged under MS–DRG 469 or 470.
- The beneficiary initiates an LEJR episode under BPCI Models 1, 2, 3 or 4.

We are modifying our proposal for canceling an episode when a beneficiary dies during an anchor hospitalization. Under our final policy, the following circumstance would also cancel an episode:

- The beneficiary dies at any time during the episode.

The final policies for cancellation of an episode are set forth in § 510.210(b). We note that § 510.210(b)(4) has been revised to state that an episode is canceled if the beneficiary dies during the episode.

c. End of the Episode

LEJR procedures are typically major inpatient surgical procedures with significant associated morbidity and a prolonged recovery period that often is marked by significant PAC needs, potential complications of surgery, and more intense management of chronic conditions that may be destabilized by the surgery. In light of the course of recovery from LEJRs for Medicare beneficiaries, we proposed that an episode in the CJR model end 90 days after discharge from the acute care hospital in which the anchor hospitalization (for MS–DRG 469 or 470) took place. Hereinafter, we refer to the proposed CJR model episode duration as the ''90-day post-discharge'' episode. To the extent that a Medicare payment for included services spans a period of care that extends beyond the episode duration, we proposed that these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending.

We noted that for the vast majority of beneficiaries undergoing a hip or knee joint replacement, a 90-day post-

discharge episode duration encompasses the full transition from acute care and PAC to recovery and return to activities. We stated our belief that the 90-day post-discharge episode duration encourages acute care hospitals, physicians, and PAC providers to promote coordinated, quality care as the patient transitions from the inpatient to outpatient settings and the community.

In proposing the 90-day post-discharge duration for LEJR episodes in CJR, we took into consideration the literature regarding the clinical experiences of patients who have undergone THA or TKA procedures. In 2007–2008, the 30-day all-cause readmission rate for primary THA among Medicare beneficiaries was 8.5 percent, while the 90-day all-cause readmission rate was 11.9 percent, indicating that while the rate of readmission begins to taper after 30 days, readmissions continue to accrue throughout this 90 day window.[6] In single center studies, Schairer et al found unplanned 30-day hospital readmission rates were 3.5 percent and 3.4 percent and unplanned 90-day hospital admission rates were 4.5 percent and 6 percent for primary THA and TKA, respectively, demonstrating that the risk of readmission remains significantly elevated from 30 through 90 days post-hospital discharge.[7] [8] Further exploring the reasons for unplanned admission for TKAs within 90 days of a knee replacement procedure, Schairer et al found that 75 percent were caused by surgical causes such as arthrofibrosis and surgical site infection. Additional information on the common reasons for hospital readmission following TKA or THA can be obtained from The American College of Surgeons National Surgical Quality Improvement Program.[9] These data identified the top 10 reasons for readmission within 30 days of a hip or knee arthroplasty:

- Surgical site infections (18.8 percent).
- Prosthesis issues (7.5 percent).
- Venous thromboembolism (6.3 percent).
- Bleeding (6.3 percent).
- Orthopedic related (5.1 percent).
- Pulmonary (3.2 percent).
- Cardiac (2.4 percent).
- CNS or CVA (2.4 percent).
- Ileus or Obstruction (2.3 percent).
- Sepsis (2.1 percent).

In addition, the authors concluded that ''readmissions after surgery were associated with new post-discharge complications related to the procedure and not exacerbation of prior index hospitalization complications, suggesting that readmissions after surgery are a measure of post-discharge complications.'' Finally, with regard to the potential for readmission for joint replacement revision within a 90-day post-discharge episode, in a twelve-year study on Medicare patients conducted by Katz, et al., the risk of revision after THA remained elevated at approximately 2 percent per year for the first eighteen months and then 1 percent per year for the remainder of the follow-up period.[10] This study suggests that a longer episode, as opposed to a shorter episode, is more likely to simulate the increased risk of revision LEJR patients face.

In order to address the complication rates associated with elective primary total hip or knee arthroplasty, we developed an administrative claims-based measure (for a detailed description of the measure see section III.D. of the proposed rule). During the development of the Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA or TKA or both, complications of elective primary total hip or knee replacement were identified to occur within specific timeframes.[11] For example, analyses done during the development of the measure as well as Technical Expert Panel opinion found that—(1) Mechanical complications and periprosthetic joint infection/wound infection are still attributable to the procedure for the 90 days following admission for surgery; (2) death, surgical site bleeding, and pulmonary embolism are still likely attributable to the hospital performing the procedure for up to 30 days; and (3) medical complications of acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock are more likely to be attributable to the procedure for up to 7 days.

Other factors further supporting a 90-day post-discharge episode duration are the elevated risk of readmission throughout this time period, as well as the fact that treatment for pneumonia is considered by American Thoracic Society guidelines to be ''health care-associated'' if it occurs up to 90 days following an acute care hospitalization of at least 2 days.[12] According to the American Academy of Orthopedic Surgeons, patients undergoing total hip replacement should be able to resume most normal light activities of daily living within 3 to 6 weeks following surgery.[13] In a small randomized controlled trial of two approaches to hip arthroplasty, average time to ambulation without any assistive device was 22–28 days.[14] According to a 2011 systematic review of studies evaluating physical functioning following THA, patients have recovered to about 80 percent of the levels of controls by 8 months after surgery.[15]

We also refer readers to a study by the Assistant Secretary for Planning and Evaluation (ASPE) in the U.S. Department of Health and Human Services that assessed the mean payments for acute care, PAC, and physician services grouped in the MS–DRG 470.[16] In this study, CMS payment for services following an MS–DRG 470 hospitalization were concentrated within the first 30 days following discharge, with plateauing of payments between 60- or 90-days post-discharge.

[6] Cram P, Lu X, Kates SL, Singh JA, Li Y, Wolf BR. Total Knee Arthroplasty Volume, Utilization, and Outcomes Among Medicare Beneficiaries, 1 991–2010. JAMA. 2012;308(12):1227–1236. doi:10.1001/2012.jama.11153.

[7] Schairer WW, et al. Causes and frequency of unplanned hospital readmission after total hip arthroplasty. Clin Orthop Relat Res. 2014 Feb;472(2):464–70. doi: 1 0.1007/s11999–013–3121–5.

[8] Schairer WW, et al. What are the rates and causes of hospital readmission after total knee arthroplasty? Clin Orthop Relat Res. 2014 Jan;472(1):181–7. doi: 1 0.1007/s11999–013–3030–7.

[9] Merkow RP, Ju MH, Chung JW, et al. Underlying Reasons Associated With Hospital Readmission Following Surgery in the United States. JAMA. 2015;313(5):483–495. doi:10.1001/jama.2014.18614.

[10] Katz JN, et al. Twelve-Year Risk of Revision After Primary Total Hip Replacement in the U.S. Medicare Population. J Bone Joint Surg Am. 2012 Oct 1 7; 94(20): 1 825–1832. doi: 1 0.2106/JBJS.K.00569.

[11] Hospital Quality Initiatives. Measure Methodology. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* See Hip and Knee Arthroplasty Complications zip file under downloads. Accessed on April 10, 2015.

[12] Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. American Thoracic Society, Infectious Diseases Society of America. Am J Respir Crit Care Med. 2005;171(4):388.

[13] *http://orthoinfo.aaos.org/topic.cfm?topic=A00377.*

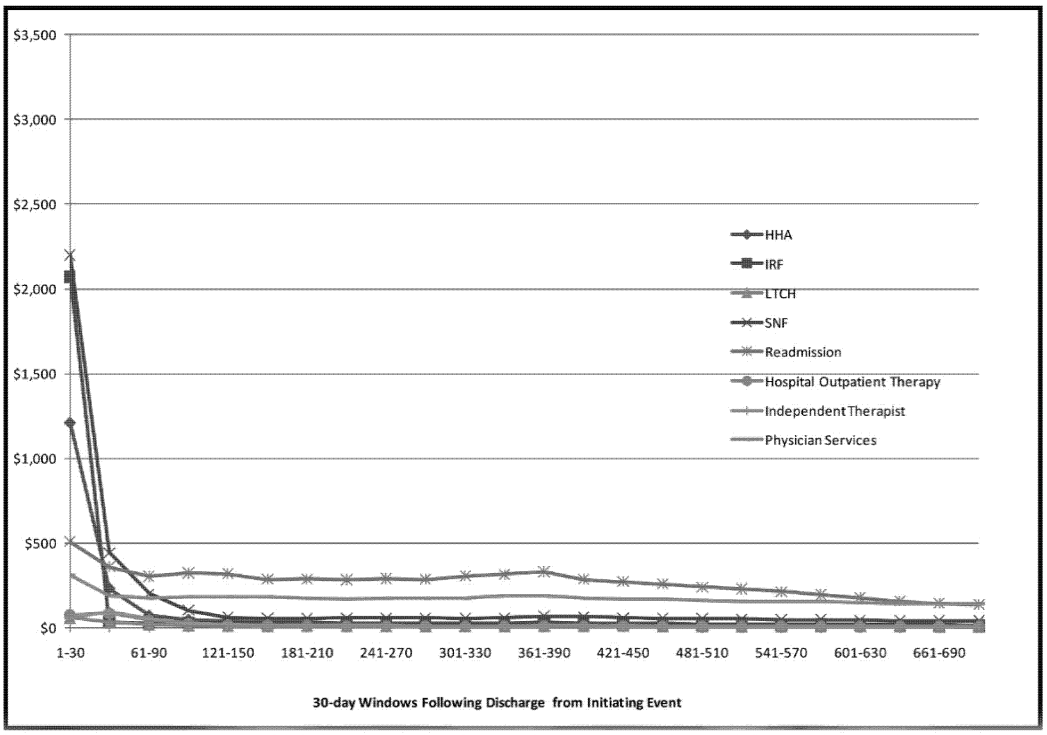
[14] Taunton MJ, et al. Direct Anterior Total Hip Arthroplasty Yields More Rapid Voluntary Cessation of All Walking Aids: A Prospective, Randomized Clinical Trial The Journal of Arthroplasty. Volume 29, Issue 9, Supplement, September 2014, Pages 169–172.

[15] Vissers MM, et al. Recovery of Physical Functioning After Total Hip Arthroplasty: Systematic Review and Meta-Analysis of the Literature. Physical Therapy May 2011 vol. 91 no. 5 615–629.

[16] Post-Acute Care Episodes Expanded Analytic File. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. April 2011.

## Figure 1

**Mean Acute, PAC, and Physician Payments Per PAC User Following Discharge From an Acute Initiating Event, by Type of Claim, MS-DRG 470, "Major Joint Replacement or Reattachment of Lower Extremity w/o MCC"**




Note: All initiating events occurred in 2006. Twenty-four 30-day windows were constructed following discharge from the initiating event to follow service use for 2 years.

Source: RTI analysis of 2006, 2007, and 2008 Medicare claims (M3MM181).

Finally, payment and length of stay analyses found the average length of stay in PAC during a 90-day post-discharge episode for MS–DRG 470 to be 47.3 days, indicating that a longer period post-discharge of 90 days is reasonable as a proposal to end the episode of care.[17] We noted that these analyses did not include any time between hospital discharge and the start of PAC.

TABLE 6—COST AND LENGTH OF STAY STATISTICS FOR MS–DRG 470 FOR VARIOUS EPISODE DURATIONS

| Statistics for DRG 470 (2006 data) | 30-day episode | 60-day episode | 90-day episode |
|---|---|---|---|
| Mean Medicare spending per hospital discharge (acute+PAC+physician) | $18,838 | $20,343 | $21,125 |
| Mean payment for anchor hospitalization | $10,463 | $10,463 | $10,463 |
| Mean payment for PAC | $6,835 | $8,339 | $9,122 |
| Mean payment for physicians (during anchor hospitalization) | $1,540 | $1,540 | $1,540 |
| Mean payment for readmission (includes all PAC users, even if no readmission occurs during the episode) | $550 | $929 | $1,242 |
| Mean length of stay (LOS) for PAC | 25.5 days | 39.6 days | 47.3 days |

**Note:** Data are per PAC user (88% of beneficiaries hospitalized under MS–DRG 470 are discharged to PAC). PAC users are defined as beneficiaries discharged to SNF, IRF, or LTCH within 5 days of discharge from the index acute hospitalization, or discharged to HHA or hospital outpatient therapy within 14 days of discharge from the index acute hospitalization. Mean LOS for PAC does not include any gap between hospital discharge date and start of PAC.

Other tests of bundled payment models for hip and knee replacement have used 90-day post-discharge episodes.[18] We also noted that despite BPCI Model 2 allowing participants a choice between 30-, 60-, or 90-day post-discharge episodes, over 86 percent of participants have chosen the 90-day post-discharge episode duration for the

[17] Analysis of Post-Acute Care Episode Definitions File. *http://innovation.cms.gov/initiatives/bundled-payments/learning-area.html.*

[18] Ridgely MS, et al. Bundled Payment Fails To Gain A Foothold In California: The Experience Of The IHA Bundled Payment Demonstration. Health Affairs, 33, no.8 (2014):1345–1352.

LEJR episode. Furthermore, a 90-day post-discharge episode duration aligns with the 90-day global period included in the Medicare Physician Fee Schedule (MPFS) payment for the surgical procedure.

We also considered proposing a 60-day post-discharge episode duration, but the full transition of care following LEJR would exceed this window for some beneficiaries, especially those who are discharged to an institutional PAC provider initially and then transition to home health or outpatient therapy services for continued rehabilitation. According to a report from ASPE on Medicare beneficiaries receiving PAC following major joint replacement in 2006, 13 percent first receive SNF services and then receive HHA services—with a total mean episode duration of 56.8 days.[19] An additional 9.2 percent receive HHA services first and then receive outpatient therapy services—with a total mean episode duration of 78.7 days. Finally, 6.7 percent receive IRF services first and then HHA services (total mean length of stay 55.3 days), and 4.8 percent receive SNF services first and then outpatient therapy services (total mean length of stay 71.5 days). The remainder only receives one type of PAC.

Therefore, in order to be inclusive of most possible durations of recovery, and services furnished to reach recovery, we proposed the 90-day post-discharge episode duration for CJR. We stated our belief that beneficiaries will benefit from aggressive management and care coordination throughout this episode duration, and hospitals will have opportunities under CJR to achieve efficiencies from care redesign during the 90-day post-discharge episode period.

We sought comment on our proposal to end the episode 90 days after the date of discharge from the anchor hospitalization, as well as on the alternative we considered of ending the CJR episode 60 days after the date of discharge.

The following is a summary of the comments received and our responses.

*Comment:* Most commenters supported the 90-day post-discharge episode duration. Many of these commenters provided rationales for supporting the 90-day duration (as compared to 60 days or other shorter durations), such as: It is a clinically appropriate length to manage an LEJR to recovery; it creates strong incentives for collaboration for multiple providers across the care continuum that improves care transitions and care coordination; it will promote better long-term results; it aligns with quality measures; and it is the most popular timeframe selected for BPCI Model 2. Some of these commenters asserted that a shorter duration is not sufficiently long to capture the vast majority of issues arising directly from LEJR procedures and could put beneficiary care at risk by encouraging providers to reduce utilization inappropriately or shift utilization outside of an episode.

A few commenters supported a 90-day episode duration, but recommended that we revise the 90-day post-discharge episode duration to begin from the date of surgery instead of discharge, thereby aligning the episode with the MPFS global surgical period and billing policies. A commenter who appeared to believe that CMS proposed to begin the CJR episode immediately after discharge from the anchor hospitalization and extend the episode 90 days post-hospital discharge, rather than upon admission for the anchor hospitalization as CMS actually proposed, asserted that beginning the episode after hospital discharge would make it difficult to understand and account for patient acuity changes within the episode in the post-discharge period as the hospital length-of-stay is related to the PAC acuity of the beneficiary following hospital discharge, especially if the beneficiary has comorbidities. In other words, the commenter believed that beneficiaries with comorbidities would be more likely to have longer anchor hospitalizations and associated higher intensity of PAC services, yet CMS would not understand these relationships if the anchor hospitalization was not included in the episode.

Several commenters supported a 60-day post-discharge episode duration because LEJR patients are nearly fully recovered within 60 days. Some commenters asserted that PAC services associated with LEJR rarely occur after 60 days post-discharge; some commenters cited data that the majority of services for patients with LEJR surgery occur within two months of discharge with only a 6.2 percent change in the total cost of an episode between a 60-day episode and a 90-day episode. Some of these commenters asserted that a 60-day episode would be sufficient to evaluate quality and cost, and a longer duration would increase the financial risk for hospitals without providing significant value to CMS. Some commenters asserted that a 90-day duration increases the risk that unrelated random events that occur well after surgery will disadvantage the hospitals by unfairly impacting participants' performance.

Some commenters recommended a hybrid approach, with every service within the first 30 days post-discharge assumed to be related unless specifically excluded, and services in days 31–90 included only if they meet specified criteria for relatedness.

Some commenters recommended that the episode end prior to 60 days post-discharge. A commenter recommended an episode length of 45 to 60 days, asserting that hospital admissions past the 45 to 60 day window would be for chronic medical admissions that are unrelated to the LEJR procedure. A few commenters recommended that we limit the episode to 30 days citing various rationales, such as: A SNF stay must commence within 30 days of a hospitalization; 30 days better aligns with other quality improvement initiatives such as readmissions; analyses by Medicare Payment Advisory Commission (MedPAC) and the Congressional Budget Office that found that the majority of a bundled payment's episode costs are incurred during the first 30 days; and hospitals may find it difficult to manage follow-up care after 30 days if patients have more than one residence. Several commenters asserted that multiple factors can exacerbate comorbidities in the period beyond 30 days post-operatively, and a model of longer duration that broadly defines related services could result in participant hospitals being more cautious about selecting patients for LEJR and complex patients being discouraged from seeking LEJR procedures in a participant hospital. A few of these commenters noted that Tennessee and Arkansas only include 30 days post-discharge for unrelated chronic conditions in their bundled payment episodes. A commenter shared its experience that, while nearly all patients are diligent about keeping 14-day and 30-day post-operative appointments, those with good outcomes are less likely to return for appointments at 90 days and beyond, resulting in potentially skewed outcomes as patients with complications are much more likely to keep a follow-up appointment at 90 days.

Some commenters recommended giving participant hospitals the flexibility to define the episode duration, either as a duration for all of a participant hospital's LEJR episodes, or to choose a duration based on a patient's clinical condition and comorbidities. A couple of commenters

[19] Examining Post-Acute Care Relationships in an Integrated Hospital. Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. February 2009

recommended that if CMS offers participants the option to choose the duration, consistent with BPCI, CMS should lower the discount percentage for those willing to take the longer episodes. A commenter disagreed with CMS' cited rationale of the operational simplicity of a single duration for all LEJR episodes by noting that BPCI Model 2 operationalized a variety of different bundles and gave participants the choice of three durations for 48 different clinical episodes.

Other commenters suggested even longer episode durations. A commenter recommended increasing the episode duration to 150 days post-discharge to promote better long-term results and reduce the likelihood of delaying care beyond the end of the episode, specifically urging CMS to adopt a longer episode period for certain clinically-complex subpopulations with predictably longer recovery timeframes. For outcome and quality measurement purposes, some commenters recommended that participant hospitals be held accountable for a longer period, with suggestions of six months, a year, and even two to three years. A commenter recommended increasing the episode duration to two years to better manage the improvements for the entirety of the treatment. A commenter recommended increasing the episode duration to five years to account for the late effects of sub-optimal implant selection.

*Response:* We appreciate the support of many commenters for the proposed 90-day post-hospital discharge CJR model episode duration. We agree with the commenters that this relatively long episode duration should capture the great majority of health care services that are related to the episode, as well as the beneficiary's return to function and short- and medium-term health outcomes. We believe this episode duration provides participant hospitals with a substantial period of time in which to work to improve the quality and efficiency of LEJR episode performance for beneficiaries who undergo LEJR surgery at their hospital. We have substantial BPCI Model 2 experience with Awardees engaged in testing 90-day LEJR episodes, and note that the vast majority of Awardees have selected the 90-day episode duration, compared to the 30-day and 60-day alternative durations that are available in the model. Our goal is to incentivize efficient high quality care that returns people to the community, and we believe that a 90-day post-discharge duration reflects a full continuum of clinical services and transition of care following LEJR procedures for the average beneficiary, at which time the patient's functional recovery is relatively complete and the patient is able to resume most normal activities of daily living.

Due to the concentration of Medicare spending in the earlier part of the episode, we also believe that a 90-day episode duration only nominally increases the hospital's financial risk when compared to 30 or 60 days. While we understand that uncommon events during the 90-day episode may occur for an individual beneficiary, resulting in an unanticipated or unavoidable need for costly health care services, we believe that our episode definition that excludes unrelated items and services and our payment policies, namely the adjustment for high payment episodes and stop-loss policies discussed in sections III.C.3. and III.C.8. of this final rule, provide sufficient protections for participant hospitals from undue financial responsibility for the care of unrelated clinical conditions as well as for unusual circumstances. We also believe that shorter episode durations may incur a higher clinical risk for beneficiaries if participants delay services beyond the episode, and the risk to beneficiaries of this response by providers to episode payment that can be minimized by the longer 90-day episode duration that we proposed. We refer readers to sections III.F.3. and 5. of this final rule for discussion of our plans to monitor for access to care and delayed care.

In response to those commenters requesting a hybrid approach where CMS would include a broader set of related services in the 30 days following discharge from the anchor hospitalization and a more limited set of related services from days 31 to 90 because of the closer clinical link of a beneficiary's clinical conditions in the first 30 days to the events during the anchor hospitalization itself, we emphasize that the CJR model is an episode payment model where many Medicare beneficiaries who receive PAC services as part of their post-operative recovery from surgery will also have underlying health conditions that may be affected by the surgery itself and care throughout the recovery period and that require attentive, flexible management if good health outcomes are to be achieved. Because PAC services are designed to be comprehensive in nature, we believe that the same Part A and Part B services should be included throughout the episode duration because PAC providers should broadly address the beneficiary's health care needs in high quality, efficient episodes, even though the anchor hospitalization itself may be more remote from the beneficiary's health needs as the time from hospital-discharge increases. As discussed in section III.A.3. of this final rule, we have identified hospitals as the financially responsible organization for the episode, although episode quality and cost performance will clearly be related in part to the quality and efficiency of care furnished by other providers and suppliers treating the beneficiary throughout the episode. We expect that participant hospitals will develop the care pathways and partnerships with other providers and suppliers necessary for the hospital to be successful in this responsibility, and this model provides a variety of tools that should be helpful to participant hospitals, such as waivers of Medicare program rules, the opportunity to engage in certain financial arrangements, and the ability to offer certain beneficiary incentives (as discussed in sections III.C.11. and III.C.10. of this final rule, respectively).

We appreciate the interest of some commenters in significantly longer episodes than the 90 days post-hospital discharge period we proposed, in order to include the longer recovery period that some beneficiaries may require as well as to account for longer term health outcomes, because the timing or frequency of joint replacement revisions may be related to implant selection, surgical technique, or other aspects of the primary joint replacement procedure. However, as previously noted, we believe that a 90-day post-discharge duration reflects a full continuum of clinical services and transition of care following LEJR procedures for the average CJR beneficiary, and we do not believe it would be an appropriate test of the model to extend the CJR episode duration beyond 90 days post-hospital discharge to reflect the longer recovery needed by some beneficiaries. Moreover, as noted previously in this section, the CJR model focuses on the surgical procedure and the associated recovery, and at this time, we are not testing a model of longer term outcomes. Therefore, we are not going to incorporate a longer time period in the episode, and will not include periods beyond then, other than to monitor the 30-day post-episode period. The 30-day post-episode period is discussed in section III.C.8.d. of this final rule, where we describe the CJR model policy that holds participant hospitals financially responsible for significantly increased Medicare Parts A and B spending in the 30 days immediately following the end of the episode. We note that the

evaluation described in section IV. of this final rule will focus on a variety of key topics including potential unintended consequences such as cost shifting beyond the CJR model episode period and stinting on medically necessary and appropriate care. As such, CMS anticipates the examination of claims submitted beyond the 90-day episode will be incorporated in the evaluation strategy. Finally, we maintain that allowing for multiple durations would be administratively complex for a model of this scope as it would be akin to implementing multiple models concurrently, each with its own customized payment calculations, risk adjustments, and other elements. We do not believe a variable approach such as is used in BPCI, which is a voluntary model, is appropriate for this large test of LEJR episode payment for all IPPS hospitals in the selected MSAs, as it would greatly increase the administrative complexity of the CJR model. We also believe that a standard duration for all episodes is important for this test of LEJR episode payment in providing us with a larger sample of episodes of the same duration from which we can learn.

Regarding the request to align the CJR model episode duration with the MPFS by beginning the 90-day duration on the date of surgery, rather than on the date of discharge from the hospital, we do not agree with this suggestion. We believe that the 90-day global surgical period for LEJR procedures under the MPFS lends support for an episode duration under the CJR model that is similar, because beneficiaries have a significant post-operative recovery period throughout which close care coordination and management among treating providers is important to beneficiary return to function. The MPFS global payment policy sets an expectation that the operating surgeon plays a significant role in caring for beneficiaries in the typical case that extends up to 90 days following surgery. However, using this same 90-day accounting methodology under the CJR episode would lead to model episodes including variable post-discharge lengths because the duration of the anchor hospitalization, which can vary substantially, would count toward the 90 days. We are interested in testing under the CJR model an episode duration that is most likely to cover the time for the beneficiary's full recovery and return to the community so we believe that including a standard length of 90 days post-hospital discharge is the best way to ensure that each CJR beneficiary's episode includes the same length of post-hospital discharge recovery in the episode. We do not believe the minor 90-day definitional differences between this model and the MPFS global billing policies for LEJR procedures should create significant problems for physicians collaborating with participant hospitals in the episode care of CJR model beneficiaries.

In response to the commenter concerned that starting the bundle after hospital discharge would make it difficult to account for patient acuity changes post-discharge under the CJR model, we want to emphasize that the CJR model episode actually begins on the day of admission for the anchor hospitalization and extends 90 days post-hospital discharge, with the day of hospital discharge counting as the first day in the 90-day post-hospital discharge period. Thus, the episode includes the full anchor hospital length-of-stay that may affect changes in patient acuity in the post-discharge period. We note that according to this episode duration definition, episodes for individual beneficiaries will have a variable total length that depends on the length of the anchor hospitalization. For example, the average length-of-stay for MS–DRG 470 is 3 days, so the average CJR model episode length for an individual beneficiary would be 92 days. The average length-of-stay for MS–DRG 569 is 6 days, so the average CJR model episode length for an individual beneficiary would be 95 days. Despite their variable total length, all CJR model episodes will include the complete anchor hospitalization and 90 days post-hospital discharge and, therefore, will include all related items and services furnished to the beneficiary throughout the episode, including those provided to address beneficiary acuity changes during the hospitalization and post-discharge period.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our proposal to end the episode 90 days after discharge from the anchor hospitalization. We are revising the definition of Episode of care to clarify that the day of discharge itself counts as the first day of the post-discharge period and adding the same clarification to § 510.210(a)

The final definitions policies for ending an episode are set forth in § 510.2 and

**§ 510.210(a).**

*C. Methodology for Setting Episode Prices and Paying Model Participants Under the CJR Model*

1. Background

As described in section II.B. of the proposed rule, we proposed to use the CJR episode payment model to incentivize participant hospitals to work with other health care providers and suppliers to improve quality of care for Medicare beneficiaries undergoing LEJR procedures and post-operative recovery, while enhancing the efficiency with which that care is provided. We proposed to apply this incentive by paying participant hospitals or holding them responsible for repaying Medicare based on their CJR episode quality and Medicare expenditure performance. The following sections describe our final decisions for the—

- Performance years covered by the model, the retrospective methodology that will be applied, and the application of two-sided risk beginning in the second year of the model;
- Adjustments that will be made to payments included in the episode;
- Episode price setting methodology;
- Use of quality performance in the payment methodology;
- Process for reconciliation;
- Adjustments for overlaps with other CMMI models and CMS programs;
- Limits and adjustments on hospitals' financial responsibility;
- Appeal procedures for reconciliation;
- Financial arrangements and beneficiary incentives; and
- Waivers of Medicare program rules.

2. Performance Years, Retrospective Episode Payment, and Two-Sided Risk Model

a. Performance Period

We proposed that the CJR model would have 5 performance years. The performance years would align with calendar years, beginning January 1, 2016. Table 7 includes details on which episodes would be included in each of the 5 performance years.

TABLE 7—PROPOSED PERFORMANCE YEARS FOR CJR MODEL

| Performance year | Calendar year | Episodes included in performance year |
|---|---|---|
| 1 | 2016 | Episodes that start on or after January 1, 2016, and end on or before December 31, 2016. |
| 2 | 2017 | Episodes that end between January 1, 2017, and December 31, 2017, inclusive. |
| 3 | 2018 | Episodes that end between January 1, 2018, and December 31, 2018, inclusive. |
| 4 | 2019 | Episodes that end between January 1, 2019, and December 31, 2019, inclusive. |
| 5 | 2020 | Episodes that end between January 1, 2020, and December 31, 2020, inclusive. |

Under our proposal, all episodes tested in this model would have begun on or after January 1, 2016 and ended on or before December 31, 2020. We noted that this definition would result in performance year 1 being shorter than the later performance years in terms of the length of time over which an anchor hospitalization could occur under the model. We also noted that some episodes that began in a given calendar year may be captured in the following performance year due to the episodes ending after December 31st (for example, episode beginning in December 2016 and ending in March 2017 would be part of performance year 2). We stated our belief that 5 years would be sufficient time to test the CJR model and gather sufficient data to evaluate whether it improves the efficiency and quality of care for an LEJR episode of care. Further, having fewer than 5 performance years may not provide sufficient time or data for evaluation. The 5-year performance period is consistent with the performance period used for other CMMI models (for example, the Pioneer Accountable Care Organization (ACO) Model).

The following is a summary of the comments received and our responses.

*Comment:* Several commenters supported our proposal for a 5-year performance period as well as our proposed start date of January 1, 2016. However, a substantial number of commenters expressed concerns over the proposed start date and requested that we delay implementation of the model. Most of these commenters expressed concerns about the ability of participants to successfully participate in the model, given the proposed timeframes. Commenters noted that participants would need additional time for activities such as developing a new infrastructure with respect to provider networks, which would include identifying and establishing contracts with collaborators as well as determining appropriate incentives and gainsharing structures; identifying and developing new care pathways and performance metrics; and developing as well as modifying accounting and IT systems. In particular, a number of commenters expressed concern with the proposed start date in light of the requirement that hospitals begin to assume risk in the second year of the model, which is discussed further later in this section. Moreover, given variation in hospital preparedness, these kinds of issues could be particularly acute for certain kinds of hospitals, for example, smaller hospitals or those with more limited resources. Also, as discussed in section III.E of this final rule, commenters noted that their ability to implement the previously stated changes would be impeded by not having received baseline and episode-level data from CMS until after the proposed start date. Commenters indicated that these data would be essential to identifying opportunities and strategies for quality and efficiency improvement, and that the model should be delayed until after they have had a chance to review and understand their own episode data.

We also received comments suggesting that implementation of the model is premature and that it should be delayed until certain actions or events have occurred, for example, until certain quality measures have been developed, data required under the Improving Medicare Post Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted October 6, 2014) (IMPACT Act) have been collected or analyzed, or CMS has considered the results of other bundled payment models such as BPCI. For example, several commenters requested a phased implementation of the CJR model, due to the limited evaluation results that have been publicly released to date for BPCI, and to allow for testing and monitoring of the CJR model prior to full implementation. Another commenter asserted that a phased-in approach to implementing CJR is appropriate, given that while episode-based payment models have shown potential to reduce cost, rigorous studies and evaluation data on episode-based payment models are limited. Some commenters expressed the view that CMS' timeline ignores multiple competing mandates that hospitals and other providers have, for example, ICD–10–CM implementation as well as EHR Meaningful Use and other quality-related programs.

In addition, we received a comment urging a delayed start date due to concerns on how requirements with respect to the civil monetary penalty (CMP) law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), or the physician self-referral prohibition (section 1877 of the Act) would apply under the model. For example, a commenter noted that the proposed rule offered insufficient protection from certain statutory and regulatory risks associated with developing coordinated care arrangements among providers and that significant ambiguity and challenges existed with respect to compliance with these requirements.

Commenters also stated that in contrast to our proposed start date for the CJR model, CMS allowed voluntary BPCI participants, who were more likely to be well positioned to participate in an episode-based payment model, at least one year to consider their episode data, yet many of them likely found the program and timing demands challenging. Further, mandating the program, especially for unprepared participants, could result in even greater challenges, and increase the chance of failure and disruption of health care services for Medicare beneficiaries.

Some commenters offered examples of how, in their view, implementing the model by the proposed start date could result in unintended consequences such as reduced access for beneficiaries or lower care quality. For example, commenters suggested that the proposed timeframe could cause hospitals to make care redesign choices that reduced access for beneficiaries or certain kinds of beneficiaries such as those who posed greater risk or that care quality could be compromised because participants would have had insufficient time to implement new care practices.

Given these concerns, commenters generally requested that we delay the start date by a specific period of time, for example, by three months, six months, nine months or a year, with most commenters requesting a delay of nine months to a year. Some

commenters recommended delay periods of two years or more. In some cases, commenters tied their proposed delay period to an event, for example, some period of time subsequent to having received baseline and episode-level data from CMS. Some commenters requested that only the mandatory aspect of the model be delayed, allowing providers willing to participate the opportunity to do so or, in the event of a delayed start date, providers be permitted to voluntarily opt-in to the model prior to the date of implementation. As such, providers who had begun to prepare for the model could begin to generate cost savings while driving improvements in quality and patient experience for LEJR patients.

*Response:* We appreciate the comments we received in support of our proposed performance period and start date. We also appreciate and are persuaded by comments expressing concerns that our proposed start date does not provide sufficient time for participants to implement the kinds of changes needed to successfully participate in the model, particularly given that baseline data would not be available until after our proposed start date of January 1, 2016. Accordingly, this final rule will delay the start date of the model to April 1, 2016. Also, as indicated in section III.E.4 of this rule, we intend to make participating hospitals' baseline data available upon request in advance of the April 1, 2016 start date, which will allow participants the opportunity to assess their baseline data as they consider changes to their care practices in advance of the model's start date. Also, as discussed in section III.C.8. of this final rule, we are reducing the potential risk to participants in Year 2 by lowering the stop-loss limit from 10 percent to 5 percent (and from 20 percent to 10 percent in Year 3). We believe that these changes will both facilitate participants' abilities to be successful under this model and allow for a more gradual transition to full financial responsibility under the model.

Table 8 includes details on which episodes would be included in each of the 5 performance years under this delay.

TABLE 8—PERFORMANCE YEARS FOR CJR MODEL

| Performance year | Calendar year | Episodes included in performance year |
|---|---|---|
| 1 | 2016 | Episodes that start on or after April 1, 2016, and end on or before December 31, 2016. |
| 2 | 2017 | Episodes that end between January 1, 2017, and December 31, 2017, inclusive. |
| 3 | 2018 | Episodes that end between January 1, 2018, and December 31, 2018, inclusive. |
| 4 | 2019 | Episodes that end between January 1, 2019, and December 31, 2019, inclusive. |
| 5 | 2020 | Episodes that end between January 1, 2020, and December 31, 2020, inclusive. |

Under this revised schedule, all episodes tested in this model will have begun on or after April 1, 2016 and ended on or before December 31, 2020. Additional discussion on how this revised performance year schedule affects the use of quality measures for the model and the timeline for the reconciliation process is included in sections III.C.5. and III.C.6. of this final rule.

We do not agree that a longer delay is needed. Hospital participants will not be financially responsible for repayment to Medicare until the second performance year of the model. In addition, as discussed in section III.C.8. of this final rule, we have further limited financial risk to hospitals in performance years 2 and 3 by lowering stop-loss limits; specifically, from 10 percent to 5 percent in Year 2, and from 20 percent to 10 percent in Year 3. Finally, while we note that commenters are correct that voluntary BPCI participants received claims data prior to taking on risk under the BPCI model, and in some cases had more than a year to prepare for participation in BPCI, we believe that providing claims data to CJR participants in early 2016 and beginning the model April 1, 2016 is appropriate for several reasons. First, we note that under BPCI, voluntary participants in Phase I had the option of receiving claims data for multiple episodes, up to the 48 clinical episodes included in the BPCI initiative. The CJR model will only include one type of episode, and as such we believe it is reasonable for hospitals to begin to analyze data and identify care patterns and opportunities for care redesign for this episode in our stated implementation timeline. We also note that due to the gradual implementation of downside risk, we expect that hospitals would spend the first performance year of the model analyzing data, identifying care pathways, forming clinical and financial relationships with other providers and suppliers, and assessing opportunities for savings under the model, utilizing the quarterly claims data we provide to them. This is similar to the approach we took to allow hospitals to participate in Phase I of BPCI prior to entering Phase II (the risk-bearing phase). As noted in this section, participant hospitals would also be eligible to receive reconciliation payments for performance year 1 if actual spending is below the target price. We believe that our implementation timeline is reasonable, given the financial opportunity for hospitals to earn reconciliation payments for performance year 1 and the gradual transition to financial responsibility.

We are also not persuaded by commenters that implementation of the model is premature or that it should be delayed until results for BPCI or other episode-based payment models are available. While we anticipate that the BPCI model will offer valuable information that should assist CMS in developing bundling payment models, the CJR model will offer additional insights that are not available under the BPCI model; in particular, insights with respect to bundling payment models on a mandatory rather than voluntary basis. Thus, we will be able to observe how a bundling payment model might work with participants that would otherwise not participate in such a model. As such, we expect the results from this model should produce data that are more broadly representative than what might be achieved under a voluntary model. Also, this model tests a different target pricing approach than the one used in BPCI. BPCI uses a purely participant-specific pricing approach, rewarding participants for improving based on their historical performance. While this may incentivize historically less efficient participants to improve, there may not be as much incentive for already efficient participants. The regional target pricing approach for this model, though, would consider a participant hospital's performance relative to its regional peers. As part of this test, we will learn whether our alternative pricing approach in this model will better incentivize participants who are already delivering high quality and efficient care while

still incentivizing historically less efficient providers to improve. We would not be able to test such a regional pricing approach under a purely voluntary model because it is likely that only the already high quality and efficient providers would sign up.

We would note that we have released final evaluation results from the ACE demonstration, which determined that the demonstration led to reduced episode spending with no adverse impact on quality of care. Further, we note that the significant level of voluntary participation in BPCI, as well as high participation in LEJR episodes in particular in all BPCI models, signify the potential for financial opportunity for both hospitals and CMS to achieve savings and improve quality of care through an episode-based payment model targeting LEJR procedures. As further evaluation results for BPCI and other models are available, we will make such information available to the public, and if necessary, could incorporate lessons learned into the CJR model. In addition, in section III.F. of this final rule, we detail our plans to monitor care to ensure beneficiaries' access to quality and timely health care is maintained under the CJR model.

While we acknowledge the benefits of having more rigorous evidence to support the success of episode-based payment models, we believe that the aforementioned findings and encouraging preliminary evaluation data from our prior and current bundled payment models and demonstrations support our plan to more broadly test the model's effectiveness at this time. Moreover, the mission of the Innovation Center is to test models of care that reduce spending while maintaining or improving the quality of care furnished to Medicare, Medicaid and CHIP beneficiaries. Testing this model will provide additional information for CMS and providers on successful payment structures and care redesign strategies.

We also disagree that the model should be delayed simply because other similar efforts are currently ongoing. Rather, we would note that it is not uncommon for CMS to test multiple similar models concurrently rather than sequentially. For example, CMS currently has multiple primary care-focused models in testing, the Comprehensive Primary Care Initiative (CPCI) and the Multi-Payer Advanced Primary Care Practice (MAPCP) models. In addition, CMS has a permanent ACO program (the Medicare Shared Savings Program), as well as multiple other ACO models in the testing phase. We believe our decision to test the CJR model at this time is consistent with the approach taken for other models and programs to test payment models that may be similar in design but are targeted at different groups of providers. Such an approach provides CMS with additional information on the potential success of various model and program aspects and design features.

Likewise, we do not agree that the model should be delayed until certain other actions have occurred (for example, after additional quality measures have been developed or data required under the IMPACT Act have been analyzed) or because of the multiple competing mandates faced by hospitals and other providers. Since the Medicare program's inception, providers have and will continue to contend with constantly evolving statutory and administrative requirements that often require them to make concurrent changes in their practices and procedures. We do not believe the CJR model is dissimilar to those requirements.

As stated previously, some commenters urged a delayed start date due to concerns on how requirements with respect to the CMP law (sections 1128A(a)(5), (b)(1) and (b)(2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), or the physician self-referral prohibition (section 1877 of the Act) would apply under the model. In response, we would note that for programmatic reasons discussed elsewhere in this final rule and to give providers additional time to ensure compliance with applicable laws, we are delaying the start date of the model to April 1, 2016.

Also as discussed earlier in this section, some commenters pointed to the potential for unintended consequences that could result from our proposed start date, including impediments to beneficiary access and reduced quality of care. As discussed in section III.D of this final rule, we are including quality measures for purposes of evaluating hospitals' performance both individually and in aggregate across the model. Also, as discussed in section III.F of this final rule, we are making final policies and actions to monitor both care access and quality. We believe these features will help ensure that beneficiary access to high quality care is not compromised under the model.

*Final Decision:* We are modifying our proposed policy on the model performance years and establishing April 1, 2016 as the start date for the model. Accordingly, we are replacing ''January 1, 2016'' in § 510.200(a) with ''April 1, 2016.''

b. Retrospective Payment Methodology

As described in section III.B. of the proposed rule, we proposed that an episode in the CJR model begins with the admission for an anchor hospitalization and ends 90 days post-discharge from the anchor hospitalization, including all related services covered under Medicare Parts A and B during this timeframe, with limited exclusions and adjustments, as described in sections III.B., III.C.3., and III.C.7. of the proposed rule. The episodes would be attributed to the participant hospital where the anchor hospitalization occurred.

We proposed to apply the CJR episode payment methodology retrospectively. Under this proposal, all providers and suppliers caring for Medicare beneficiaries in CJR episodes would continue to bill and be paid as usual under the applicable Medicare payment system. After the completion of a CJR performance year, Medicare claims for services furnished to beneficiaries in that year that were included in the model would be grouped into episodes and aggregated, and participant hospitals' CJR episode quality and actual payment performance would be assessed and compared against episode quality thresholds and target prices, as described in sections III.C.5. and III.C.4. of the proposed rule, respectively. After the participant hospitals' actual episode performance in quality and spending are compared against the previous episode quality thresholds and target prices, we would determine if Medicare would make a payment to the hospital (reconciliation payment), or if the hospital owes money to Medicare (resulting in Medicare repayment). The possibility for hospitals to receive reconciliation payments or be subject to repayment (note: participant hospitals would not be subject to repayment for performance year 1) was further discussed in section III.C.2.c. of the proposed rule.

We considered an alternative option of paying for episodes prospectively by paying one lump sum amount to the hospital for the expected costs of the 90-day episode. However, we believed such an option would be challenging to implement at this time given the payment infrastructure changes for both hospitals and Medicare that would need to be developed to pay and manage prospective CJR episode payments. We noted that a retrospective episode payment approach is currently being utilized under BPCI Model 2. Also, we expressed our belief that a retrospective payment approach can accomplish the objective of testing episode payment in

a broad group of hospitals, including financial incentives to streamline care delivery around that episode, without requiring core billing and payment changes by providers and suppliers, which would create substantial administrative burden. However, we sought comment on potential ways to implement a prospective payment approach for CJR in future performance years of the model.

The following is a summary of the comments received and our responses.

*Comment:* Commenters submitted mixed responses on our proposed retrospective payment methodology. Many comments we received expressed support for our proposed retrospective model. Some of these commenters indicated that, since it would build upon existing payment system infrastructures and processes, a retrospective model would be most administratively feasible and straightforward as well as involve fewer infrastructure changes and logistical challenges than would be required under a prospective model. A commenter noted that a retrospective model would allow providers to gain experience with a bundling payment model without altering existing revenue cycle practices. Further, the availability of fee-for-service payments under a retrospective model would maintain a predictable cash flow for participants in the model.

Some commenters expressed support for the proposed retrospective methodology provided that certain conditions existed. For example, a commenter expressed support for this methodology provided that payment reconciliation could be available on a quarterly basis. Another commenter supported the retrospective methodology provided that beneficiaries had access to any provider they chose and were not limited to those with whom a hospital had a contractual arrangement.

*Response:* We appreciate the comments we received that were in support of our proposed retrospective payment methodology, and concur with commenters' views on some of the benefits of this model. As discussed further in section III.C.6. of this final rule, we are making final our proposed reconciliation on an annual basis. Also, as further discussed in section III.F.2. of this final rule, because hospitals in selected geographic areas will be required to participate in the model, individual beneficiaries will not be able to opt out of the CJR model. However, the payment model does not limit a beneficiary's ability to choose among Medicare providers and suppliers or the range of services that are available to them. Beneficiaries may continue to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services. Also, although the proposed model would allow participant hospitals to enter into sharing arrangements with certain providers and suppliers and these preferred providers and suppliers may be recommended to beneficiaries as long as those recommendations are made within the constraints of current law, hospitals may not restrict beneficiaries to any list of preferred or recommended providers and suppliers that surpass any restrictions that already exist under current statutes and regulations.

*Comment:* In addition to the many commenters supporting our proposed retrospective methodology, we received many other comments that opposed our proposal and expressed support for some type of prospective payment model. Some commenters expressed the view that our proposed model was complex, complicated by variation in payment policies across Medicare FFS payment models, and needed further refinement. Others stated that as compared to a prospective payment model, a retrospective model is less effective at holding providers accountable or in stimulating the kinds of behavior changes that are needed to achieve the goals of the program. For example, because providers are expected to change their behavior in anticipation of a reward that might occur several months later, the model diminishes the incentive for providers to change their behavior. Moreover, bonuses and penalties are not sufficiently correlated with performance. Further, a retrospective model could limit the availability of resources for providers to invest in the changes needed to support and sustain behavior change and high-quality care.

Some of the criticisms we received focused on the potential effects of a retrospective model on beneficiaries' costs. For example, some commenters expressed concerns on whether beneficiaries would or even could see cost-sharing reductions when a provider achieves savings under a retrospective model. Another comment suggested that as compared to a prospective model, payments under a retrospective model are more difficult to be incorporated into tools designed to help consumers shop for facilities and providers and reduced pricing predictability for the consumer.

In light of these concerns, many commenters proposed that CMS adopt or eventually transition to some kind of prospective payment model or hybrid model. Commenters suggested that doing so would improve accountability for costs and quality, strengthen risk/reward relationships, better support efforts to transition away from FFS, encourage providers to adhere to evidence-based clinical guidelines, reduce unnecessary or duplicative care, and help participants invest early in supportive resources, such as health information technology, care coordination tools, and infrastructure development to support accountability for quality and costs. A commenter offered the view that information technology solutions are now available that support prospective payment models with minimal burden and disruption to hospitals—concerns that have discouraged the adoption of prospective models.

Some examples of prospective models that were suggested would be for CMS to—

- Establish an extended DRG that includes hospital, physician, and PAC services for some period of time (for example, 30, 60, 90 days);
- Make a prospective payment to hospitals that are then distributed to their partners based on volume, acuity, quality, and efficiency;
- Withhold some percentage of the total payment that would be intended for downstream partners. Hospitals would subsequently distribute these payments to partners based on their ability to meet quality and efficiency targets;
- Move toward a prospectively negotiated case rate to foster collaboration among all clinicians involved in patient care and provide predictable pricing. For example, give facilities a financial incentive to assume the greater risk and uncertainty inherent in a prospective bundle by reducing or eliminating the two percent discount from the payment benchmark or narrowing the definition of ''related care'' in the 90-day post-discharge; and
- Allow physicians to lead a team where the participating physician and their patient decide which other providers and suppliers would be involved in and what the treatment plan would be for the episode. The team would designate or create a jointly governed management organization that would be paid through new prospective episode codes. Other providers, including the hospital, could be paid by that same organization or through existing Medicare payment systems. Medicare would pay a single bundled

payment amount to cover the costs of all of the services in that episode. The hospital and other providers and suppliers on the team could be paid either through the management organization or through traditional Medicare payment systems, but only by one of these sources. Amounts paid through traditional payment systems would be deducted from the amount paid to the management organization.

In addition to comments supporting a prospective payment model, we received comments explicitly expressing concern about adopting such a model. For example, a commenter expressed the view that non-hospital providers and suppliers, including physicians and PAC providers, would likely be concerned with a policy that would allow hospitals complete authority to allocate payments among participating providers and suppliers or to be empowered with functions and authorities typically associated with Medicare Administrative Contractors (MACs). Moreover, a prospective payment methodology would exacerbate anti-competitive concerns with respect to the proposed model in general.

*Response:* We appreciate the comments we received in opposition to our proposed retrospective model. While we believe that our proposed retrospective payment model would be effective in encouraging providers to improve care quality while better controlling the costs of the care, we also share commenters' optimism on the potential benefits and effectiveness of prospective models with respect to improving accountability for costs and quality, strengthening risk/reward relationships, better supporting efforts to transition away from FFS, and encouraging providers to adhere to evidence-based clinical guidelines while reducing unnecessary or duplicative care. We also are pleased that information technology solutions are being developed to support prospective payment models.

We agree with commenters that there are complexities and potential complications associated with a retrospective model and anticipate that further refinements will likely be needed with whatever kind of bundling model that is implemented. Therefore, we do not believe that the complexities and potential complications with our proposed model are significantly different than what occurs with other Medicare payment models, particularly any of the more novel ones. Likewise, we do not believe that such complexities or complications would be mitigated simply by adopting a prospective model. Moreover, both CMS and some of the commenters have noted that adoption of a prospective model could result in potentially significant complexities and logistical issues as well.

We also do not agree with the view suggesting that adoption of a retrospective model could limit the availability of resources for providers to invest in the changes needed to improve care quality and costs. Under our retrospective model, participant hospitals and other providers and suppliers will continue to bill and be paid under FFS Medicare as they would in the absence of the model that should result in a revenue stream comparable to what they would be absent the model, all else equal.

While we agree with the comment stating that beneficiaries will not see a reduction in their cost-sharing for joint replacement services under this model, we do not see this as being unique to the CJR model or a reason to not test it. To the contrary, if successful, our model will improve the quality of care and outcomes for these beneficiaries as well as better control costs of care. For example, if successful, we believe the model could help to limit or mitigate avoidable costs incurred by these beneficiaries such as costs associated with avoidable hospital readmissions. Last, we also do not see the potential challenges of integrating a retrospective payment methodology into sites designed to compare health care options as a reason to not test our proposed model or as being an insurmountable problem.

Based on the comments that we received, we believe there is support for both prospective and retrospective payment models. We also continue to believe that a retrospective payment model can accomplish the objective of testing episode payments with a broad group of hospitals, by including financial incentives that will streamline care delivery while producing less administrative burden for providers than would be possible with a prospective model. Accordingly, we will be implementing a retrospective payment model at this time as we had proposed. We appreciate the various examples of prospective models that commenters suggested for CMS' consideration, and will consider these examples along with other options to potentially be tested in the future.

*Final Decision:* After considering the public comments we received, we are finalizing our proposal to implement a retrospective payment model.

c. Two-Sided Risk Model

We proposed to establish a two-sided risk model for hospitals participating in the CJR model. We proposed to provide episode reconciliation payments to hospitals that meet or exceed quality performance thresholds and achieve cost efficiencies relative to CJR target prices established for them, as was defined later in sections III.C.4. and III.C.5. of the proposed rule. Similarly, we proposed to hold hospitals responsible for repaying Medicare when actual episode payments exceed their CJR target prices in each of performance years 2 through 5, subject to certain proposed limitations discussed in section III.C.8. of the proposed rule. Target prices would be established for each participant hospital for each performance year.

We proposed that hospitals will be eligible to receive reconciliation payments from Medicare based on their quality and actual episode spending performance under the CJR model in each of CJR performance years 1 through 5. Additionally, we proposed to phase in the responsibility for hospital repayment of episode actual spending if episode actual spending exceeds their target price starting in performance year 2 and continuing through performance year 5. Under this proposal in performance year 1, participant hospitals would not be required to pay Medicare back if episode actual spending is greater than the target price.

We considered an episode payment structure in which, for all 5 performance years of the model, participant hospitals would qualify for reconciliation payments if episode actual spending was less than the episode target price, but would not be required to make repayments to Medicare if episode actual spending was greater than the episode target price. However, we noted our belief that not holding hospitals responsible for repaying excess episode spending would reduce the incentives for hospitals to improve quality and efficiency. We also considered starting the CJR payment model with hospital responsibility for repaying excess episode spending in performance year 1 to more strongly align participant hospital incentives with care quality and efficiency. However, we stated our view that hospitals may need to make infrastructure, care coordination and delivery, and financial preparations for the CJR episode model, and that those changes can take several months or longer to implement. With this consideration in mind, we proposed to begin hospitals' responsibility for repayment of excess episode spending

beginning in performance year 2 to afford hospitals time to prepare, while still beginning some incentives earlier (that is, reconciliation payments in year 1) to improve quality and efficiency of care for Medicare beneficiaries. We solicited comment on the proposed incentive structure for CJR.

In an effort to further ensure hospital readiness to assume responsibility for circumstances that could lead to a hospital repaying to Medicare actual episode payments that exceed the episode target price, we proposed to begin to phase in this responsibility for performance year 2, with full responsibility for excess episode spending (as proposed in the proposed rule) applied for performance year 3 through performance year 5. To carry out this ''phase in'' approach, we proposed during the first year of any hospital financial responsibility for repayment (performance year 2) to set an episode target price that partly mitigates the amount that hospitals would be required to repay (see section III.C.4.b. of the proposed rule), as well as more greatly limits (as compared to performance years 3 through 5) the maximum amount a hospital would be required to repay Medicare across all of its episodes (see section III.C.8. of the proposed rule).

*Comment:* Several commenters expressed support for our proposal to establish downside risk for participants as well as our proposal to gradually phase-in risk beginning in year 2. We received very few comments requesting the elimination of risk from the model. A commenter suggested that it was unfair to require hospitals to bear risk given that there were no limitations on beneficiary choices. Also, some commenters suggested that CMS consider excluding specific kinds of hospitals from the model, for example small hospitals or hospitals with low volume.

Most of the comments we received, however, requested that CMS ease the glide path to downside risk by either delaying the requirement for two to three years or by incorporating features to better limit risk, for example, by adjusting stop-loss caps. Some commenters requested that we modify the CJR model to be more like a shared savings model as is used in Shared Savings Program or the Pioneer ACO model. In their view, this option would be particularly attractive to smaller organizations with lower episode volumes that face a higher risk of random episode cost variation or those with limited financial resources.

Some commenters requested these changes because of concerns that hospitals have little or no experience bearing risk and thus need additional time to be ready to do so. Other commenters stated that our proposed timeframe for implementing the model and requiring hospitals to assume risk was simply too aggressive and offered too little time for hospitals to put in place the care procedures and infrastructure needed to be successful in the model and in a position to bear risk. In recommending that CMS delay downside risk, a commenter observed that payment features of other Medicare efforts such as BPCI and the Pioneer ACO model have been refined more than once since their implementation, which suggested that more can be learned about the appropriate framework for a risk model, particularly given that the CJR model is untested.

*Response:* We appreciate the comments we received in support of our proposal to phase-in downside risk to CJR participants beginning in Year 2 of the model. We are also encouraged that very few commenters opposed a requirement for participants to assume downside risk at some point in the model.

We disagree with the view that it is unfair to require hospitals to bear risk while beneficiaries retain the ability to choose among providers. As is the case with other new payment models such as the Shared Savings Program, the CJR model is intended to identify ways to improve care quality and better control costs in the Medicare FFS program. While Medicare beneficiaries may choose between Medicare FFS and Medicare Advantage, the majority of beneficiaries—roughly two-thirds in 2015—continue to choose the former. Accordingly, it is in the interest of the Medicare program and its beneficiaries for CMS to identify new models that both maintain beneficiary choice while improving care quality and costs. Also, while we appreciate suggestions to exclude certain kinds of hospitals, for example, small hospitals or hospitals with a low-volume of cases, we believe our methodology for selecting geographic units, as discussed in section III.A.4.of this final rule, as well as additional protections for certain kinds of these hospitals, as discussed in section III.C.8.c. of this final rule sufficiently address these concerns.

We also understand that commenters would like a more gradual transition to downside risk, and in response to the commenters' concerns, CMS has taken steps for hospitals to do so. As discussed in section III.C.8. of this final rule, we are reducing the potential risk to participants in Year 2 by lowering the stop-loss limit from 10 percent to 5 percent (and from 20 percent to 10 percent in Year 3). We believe these actions should assist participants both with respect to preparing for the assumption of risk as well as reducing the level of risk they must initially bear. We do not support the proposal to change the CJR model to a shared savings model as it is inconsistent with our intent of testing whether a bundled payments model will promote quality and financial accountability for episodes of care surrounding an LEJR or reattachment of a lower extremity procedure. Last, we recognize that our model, as would any model or program, will evolve and may require some adjustments over time. To the extent that this occurs with the CJR model, we would make adjustments that were deemed necessary, as we would do with any of these other models and programs; however, we do not believe the potential for model adjustments is a reason to delay the requirement for hospitals to bear risk in the absence of data suggesting that a problem actually exists.

*Final Decision:* After considering the public comments we received, we are finalizing our proposal to phase-in risk beginning in Year 2 of the model.

3. Adjustments to Payments Included in Episode

We proposed to calculate the actual episode payment amount by summing together Medicare payments for each non-cancelled CJR episode during the model's performance year for Parts A and B claims for services included in the episode definition, as discussed in section III.B. of this final rule. We proposed three adjustments to this general approach for—(1) Special payment provisions under existing Medicare payment systems; (2) payment for services that straddle the end of the episode; and (3) high payment episodes. We noted there would be further adjustments to account for overlaps with other Innovation Center models and CMS programs; we refer readers to section III.C.7. of the proposed rule.

We did not propose to adjust hospital-specific or regional components of target prices for any Medicare repayment or reconciliation payments made under the CJR model; CJR repayment and reconciliation payments would be not be included per the episode definition in section III.B. of this final rule. We stated in the proposed rule our belief that including reconciliation payments and Medicare repayments in target price calculations would perpetuate the initial set of target prices once CJR performance years are captured in the 3-historical-years of data used to set target

prices, as described in section III.C.4. of this final rule, beginning with performance year 3 when performance year 1 would be part of the 3-historical-years. Including any prior performance years' reconciliations or repayments in target price calculations would approximately have the effect of Medicare paying hospitals the target price, regardless of whether the hospital went below, above, or met the target price in the prior performance years before accounting for the reconciliation payments or repayments. We stated in the proposed rule our intent for target prices to be based on historical patterns of service actually provided, so we did not propose to include reconciliation payments or repayments for prior performance years in target price calculations.

a. Treatment of Special Payment Provisions Under Existing Medicare Payment Systems

Many of the existing Medicare payment systems have special payment provisions that have been created by regulation or statute to improve quality and efficiency in service delivery. IPPS hospitals are subject to incentives under the HRRP, the Hospital Value-Based Purchasing (HVBP) Program, the Hospital-Acquired Condition (HAC) Reduction Program, and the Hospital Inpatient Quality Reporting Program (HIQR) and Outpatient Quality Reporting Program (OQR). IPPS hospitals and CAHs are subject to the Medicare EHR Incentive Program. Additionally, the majority of IPPS hospitals receive additional payments for Medicare Disproportionate Share Hospital (DSH) and Uncompensated Care, and IPPS teaching hospitals can receive additional payments for Indirect Medical Education (IME). IPPS hospitals that meet a certain requirements related to low volume Medicare discharges and distance from another hospital receive a low volume add-on payment. As previously stated in section III.B.2.b. of this final rule, acute care hospitals may receive new technology add-on payments to support specific new technologies or services that substantially improve the diagnosis or treatment of Medicare beneficiaries and would be inadequately paid otherwise under the MS–DRG system. Also, some IPPS hospitals qualify to be sole community hospitals (SCHs) or MDHs, and they may receive enhanced payments based on cost-based hospital-specific rates for services; whether a SCH or MDH receives enhanced payments may vary year to year, in accordance with § 419.43(g) and § 412.108(g), respectively.

Medicare payments to providers of PAC services, including IRFs, SNFs, IPFs, HHAs, LTCHs, and hospice facilities, are conditioned, in part, on whether the provider satisfactorily reports certain specified data to CMS: The Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP), the Skilled Nursing Facility Quality Reporting Program (SNF QRP), the Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP), the Home Health Quality Reporting Program (HH QRP), the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), and the Hospice Quality Reporting Program. Additionally, IRFs located in rural areas receive rural add-on payments, IRFs serving higher proportions of low-income beneficiaries receive increased payments according to their low-income percentage (LIP), and IRFs with teaching programs receive increased payments to reflect their teaching status. SNFs receive higher payments for treating beneficiaries with human immunodeficiency virus (HIV). HHAs located in rural areas also receive rural add-on payments.

ASCs have their own Quality Reporting Program (ASC QRP). Physicians also have a set of special payment provisions based on quality and reporting: The Medicare EHR Incentive Program for Eligible Professionals, the Physician Quality Reporting System (PQRS), and the Physician Value-based Modifier Program.

In the proposed rule we stated our intent with the CJR model is not to replace the various existing incentive programs or add-on payments, but instead to test further episode payment incentives towards improvements in quality and efficiency beyond Medicare's existing policies. Therefore, we proposed that the hospital performance and potential reconciliation payment or Medicare repayment be independent of, and not affect, these other special payment provisions.

We proposed to exclude the special payment provisions as discussed previously when calculating actual episode payments, setting episode target prices, comparing actual episode payments with target prices, and determining whether a reconciliation payment should be made to the hospital or funds should be repaid by the hospital.

Not excluding these special payment provisions would create incentives that are not aligned with the intent of the CJR model. Not excluding the quality and reporting-related special payment provisions could create situations where a high-quality or reporting compliant hospital or both receiving incentive payments, or those hospitals that discharge patients to PAC providers that receive incentives for being reporting compliant, may appear to be ''high episode payment'' under CJR. Conversely, lower quality or hospitals not complying with reporting programs or both that incur payment reduction penalties, or hospitals that discharge to PAC providers that are not reporting compliant, may appear to be ''low episode payment'' under CJR. Such outcomes would run counter to CJR's goal of improving quality. Also, not excluding add-on payments for serving more indigent patients, having low Medicare hospital volume, being located in a rural area, supporting greater levels of provider training, choosing to use new technologies, and having a greater proportion of CJR beneficiaries with HIV from CJR actual episode payment calculations may inappropriately result in hospitals having worse episode payment performance. Additionally, not excluding enhanced payments for MDHs and SCHs may result in higher or lower target prices just because these hospitals received their enhanced payments in one historical year but not the other, regardless of actual utilization. In the proposed rule we stated our belief that excluding special payment provisions would ensure a participant hospital's actual episode payment performance is not artificially improved or worsened because of payment reduction penalties or incentives or enhanced or add-on payments, the effects of which we are not intending to test with CJR.

In addition to the various incentive, enhanced and add on payments, sequestration came into effect for Medicare payments for discharges on or after April 1, 2013, per the Budget Control Act of 2011 and delayed by the American Taxpayer Relief Act of 2012. Sequestration applies a 2 percent reduction to Medicare payment for most Medicare FFS services.

In order to operationalize the exclusion of the various special payment provisions in calculating episode expenditures, we proposed to apply the CMS Price (Payment) Standardization Detailed Methodology described on the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350*. This pricing standardization approach is the same as used for the HVBP program's Medicare spending per beneficiary metric.

We sought comment on this proposed approach to treating special payment

provisions in the various Medicare payment systems.

*Comment:* Several commenters supported the exclusion of the various special payment provisions in calculating episode expenditures. They agreed that doing so would help isolate the effect of utilization and quality of delivered care differences and remove any distortions due to Medicare payment policies outside the control of providers.

A few commenters expressed concern about how hospitals would be paid the special payment adjustments that are removed in calculating episode expenditures. A commenter inquired whether CMS would account for vendor rebates for hip and knee implants and medical devices, because rebates are not uncommon and can impact the cost of an LEJR procedure to a hospital.

*Response:* We appreciate commenters' support to exclude the various special payment provisions in calculating episode expenditures.

As discussed in section III.C.2.b. of this final rule, we are finalizing our proposal such that all providers and suppliers caring for Medicare beneficiaries in CJR episodes will continue to bill and be paid as usual under the applicable Medicare payment system, and determination of any reconciliation payments or repayments to Medicare will be made retrospectively after the end of each performance year. Therefore, special payment adjustments will continue to be paid as usual under the applicable Medicare payment systems, but their effects will be excluded when reconciliation payment and repayment to Medicare determinations are made retrospectively. This final rule will not affect how hospitals are currently paid special payment adjustments.

Payments for hip and knee implants and medical devices will also continue as usual under the applicable Medicare payment systems. For inpatient admissions paid under IPPS, in particular, implants and medical devices not categorized as new technology add-on payment would be included in the MS–DRG payment and would not be reimbursed separately. To mirror the IPPS approach, we will not separately account for vendor rebates in the LEJR episode.

We note that as previously stated, we plan to utilize the CMS Price (Payment) Standardization approach in order to remove the effects of special payment provisions from calculations of historical and performance period episode spending. We will follow the methodology, with modifications as necessary to be consistent with our episode definition in section III.B. of this final rule and to ensure timely reporting of reconciliation results, for the performance year reconciliations, which begin 2 months after the conclusion of a performance year. We will account for the information available at the time due to claims runout, payment system updates, and the calculations necessary to fully implement the standardization methodology. We will utilize the methodology, consistent with our episode definition, for the target price calculations and subsequent reconciliation calculations 14 months after the conclusion of the performance year, in which we incorporate full claims runout and further account for overlap with other models. This approach will provide feedback and reconciliation payments, as available, to hospitals in a timely manner and as accurately as feasible, while ensuring the standardization approach is utilized for the subsequent calculation, which represents the final calculation for a given performance period.

*Comment:* Many commenters requested that CJR reconciliation payments made to participant hospitals be included when updating the set of 3-historical-years used for calculating CJR episode target prices. They stated that the participant hospitals would be providing care coordination services that may not be directly reimbursed under applicable Medicare FFS payment systems. These services would then, instead, be funded by reconciliation payments. While historical Medicare FFS claim payments would account for hospitals' costs for providing services reimbursed under Medicare FFS, they would not account for hospitals' costs for care coordination services not reimbursed under Medicare FFS. Commenters contended that if we do not include reconciliation payments when calculating target prices using the updated set of historical years, we may underestimate hospital costs and target prices.

*Response:* We agree that participant hospitals may undertake activities that promote care coordination and improved quality of care but are not directly reimbursed under applicable Medicare FFS payment systems. We appreciate commenters' suggestions to include reconciliation payments when updating the set of historical years used to calculate target prices. We also believe this logic could be extended to include repayments to Medicare to mirror the inclusion of reconciliation payments. However, in the proposed rule we did not propose an alternative to include reconciliation payments and repayments when updating the set of historical years used to calculate target prices, and because the first time this policy would take effect would be for performance year 3 (2018), we may revisit this policy in future rulemaking and allow for public comment on the aforementioned alternative. At this time we are not modifying our proposal to exclude CJR reconciliation payments and repayments to Medicare when updating the set of historical years used to set target prices.

*Comment:* A few commenters inquired whether claims from non-participating physicians or payments to physicians who have opted out of Medicare would be included for purposes of setting target prices and calculating actual episode spending for reconciliation and repayment amount calculations. Commenters contended that if claims from non-participating providers or payments to physicians who have opted out of Medicare are not included, target prices and actual episode spending may be underestimated.

*Response:* With the exception of those physicians and practitioners who have complied with our opt-out procedures (see 42 CFR 405.400 through 405.455), when a physician or supplier furnishes a service that is covered by Medicare, the physician or supplier is subject to the mandatory claim submission provisions of section 1848(g)(4) of the Social Security Act (the Act). Therefore, if a physician or supplier charges or attempts to charge a beneficiary for a service that is covered by Medicare, then the physician or supplier must submit a claim to Medicare. As a result, claims from both participating and non-participating physicians would be included in our target price and actual episode spending calculations.

Opt-out physicians are prohibited from billing and receiving payment (either directly or indirectly) from Medicare except for emergency and urgent care services provided the physician has not previously entered into a private contract with the beneficiary. Therefore, we agree that payments for services furnished by physicians who have opted out of Medicare would not be included in target price and actual episode expenditure calculations. However, we estimate only a small portion of physicians furnishing services to beneficiaries captured in the CJR model will have opted out of Medicare, and we estimate that physician services comprise less than 15 percent of the average CJR episode expenditure, and therefore we believe the impact of not capturing expenditures from physicians

who have opted out of Medicare will be small.

Additionally, there may be some participant hospitals with a disproportionately higher share of episodes for which services were furnished by physicians who have opted out of Medicare. Such participant hospitals would experience lower actual episode expenditures because payments for physicians who have opted out of Medicare would not be included. These hospitals' lower actual episode expenditures would be balanced by lower target prices because the payments for physicians who have opted out of Medicare would also be excluded in the historical episode expenditures, though this argument is primarily relevant in the early years of the CJR model before we move to 100 percent regional pricing as discussed in section III.C.4.b.(5) of this final rule. In the later years of this model, participant hospitals with disproportionately greater share of episodes for which services were furnished by Medicare opt-out physicians may unfairly benefit from regional target prices that are primarily based on the inclusion of expenditures for physician services. However, we believe this advantage to be small because physician expenditures comprise only a small portion of the average episode, and we expect very few physicians to opt out of Medicare.

*Comment:* A commenter inquired whether CMS would include IPPS capital payments in calculating target prices and actual episode expenditures, and if CMS' plan was to include them, they requested that such payments be excluded. The commenter stated that capital payments may vary by hospitals, and excluding capital payments would be consistent with the pricing standardization approach we proposed to reduce variations due to Medicare payment policies. The commenter also noted that excluding capital payments would be consistent with the approach taken in BPCI.

*Response:* In response to comments, we clarify that we will include IPPS capital payments in target price and actual episode expenditure calculations. IPPS capital payments are included in Medicare FFS payments, which we proposed to use to calculate target prices and actual episode expenditures. Consistent with our proposed treatment of special payment provisions, we do not intend to distort incentives based on IPPS capital payments that may vary across hospitals due to Medicare payment policies, as opposed to practice pattern and quality differences. By using the claims standardization approach previously described in this section, though, we will be able to remove the effect of variations due to Medicare payment policies (including wage index differences). We recognize that this approach of including IPPS capital payments would be different than the approach taken in BPCI. However, we note that other Medicare FFS payment systems, such as those for SNF and IRF, also are intended to cover providers' capital costs. Carving out the capital portion for IPPS payments would not be consistent with the inclusion of the capital portion for other Medicare FFS payment systems. Lastly, including IPPS capital payments affords participant hospitals an opportunity to achieve greater reconciliation payments if they are able to achieve efficiencies for the costs that the capital portion of IPPS payments would cover, which may or may not actually be capital costs.

*Comment:* Several commenters expressed concern about the regions that were selected for both the CJR model and the proposed HHVBP model.

*Response:* We refer readers to comments and responses to comments in section III.A.3 of this final rule for further discussion on the inclusion of regions selected for both the CJR model and the proposed HHVBP model, and we reference it here because the proposed HHVBP model would be another special payment provision that could affect Medicare payment amounts. We reemphasize that the intent of the CJR model is not to replace the various existing incentive programs or add on payments, and the claims standardization approach previously described in this section will remove the effect of any special payment provision, whether they currently exist or may be introduced in the future. Therefore, we do not believe any special payment provisions due to the proposed HHVBP model or other potential future special payment provisions to have an impact on the payments included in the CJR model target price and reconciliation calculations.

*Comment:* A commenter requested clarification on how the CJR model would interact with Medicare beneficiaries who have exhausted their benefits, and recommended that we modify Medicare beneficiaries' benefits so as to not allow their benefits to be exhausted while part of a CJR episode.

*Response:* We appreciate the commenter's suggestion. However, we did not propose any changes to Medicare beneficiaries' benefits, and we will not finalize any such changes in this final rule.

*Final Decision:* We are finalizing our proposal, without modification, to exclude special payment provisions from episode calculations. We clarify that we will include IPPS capital payments in target price and actual episode expenditure calculations. We also clarify that we will utilize the CMS Price Standardization approach previously referenced to remove the effect of any current and potential future special payment provisions. We may revisit in future rulemaking any modification to our policy to exclude reconciliation and recoupment payments when updating the historical data used to set target prices.

b. Treatment of Payment for Services That Extend Beyond the Episode

As we proposed a fixed 90-day post-discharge episode as discussed in section III.B. of the proposed rule, we stated our belief that there would be some instances where a service included in the episode begins during the episode but concludes after the end of the episode and for which Medicare makes a single payment under an existing payment system. An example would be a beneficiary in a CJR episode who is admitted to a SNF for 15 days, beginning on Day 86 post-discharge from the anchor CJR hospitalization. The first 5 days of the admission would fall within the episode, while the subsequent 10 days would fall outside of the episode.

We proposed that, to the extent that a Medicare payment for included episode services spans a period of care that extends beyond the episode, these payments would be prorated so that only the portion attributable to care during the episode is attributed to the episode payment when calculating actual Medicare payment for the episode. For non-IPPS inpatient hospital (for example, CAH) and inpatient PAC (for example, SNF, IRF, LTCH, IPF) services, we proposed to prorate payments based on the percentage of actual length of stay (in days) that falls within the episode window. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.d. of this final rule. In the prior example, one-third of the days in the 15-day length of stay would fall within the episode window, so under the proposed approach, one-third of the SNF payment would be included in the episode payment calculation, and the remaining two-thirds (because the entirety of the remaining payments fall within the 30 days after the episode ended) would be included in the post-episode payment calculation.

For HHA services that extend beyond the episode, we proposed that the

payment proration be based on the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that fall within the CJR episode. Prorated payments would also be similarly allocated to the 30-day post-episode payment calculation in section III.C.8.d. of the proposed rule. For example, if the patient started receiving services from an HHA on day 86 after discharge from the anchor CJR hospitalization and the last billable home health service date was 55 days from the start of home health care date, the HHA claim payment amount would be divided by 55 and then multiplied by the days (5) that fell within the CJR episode. The resulting, prorated HHA claim payment amount would be considered part of the CJR episode. Services for the prorated HHA service would also span the entirety of the 30 days after the CJR episode spends, so the result of the following calculation would be included in the 30-day post-episode payment calculation: HHA claim payment amount divided by 55 and then multiplied by 30 days (the number of days in the 30-day post-episode period that fall within the prorated HHA service dates).

There may also be instances where home health services begin prior to the CJR episode start date, but end during the CJR episode. In such instances, we also proposed to prorate HHA payments based on the percentage of days that fell within the episode. Because these services end during the CJR episode, prorated payments for these services would not be included in the 30-day post-episode payment calculation discussed in section III.C.8.d. of the proposed rule. For example, if the patient's start of care date for a home health 60-day claim was February 1, the anchor hospitalization was March 1 through March 4 (with the CJR episode continuing for 90 days after March 4), and the patient resumed home care on March 5 with the 60-day home health claim ending on April 1 (that is, April 1 was the last billable service date), we would divide the 60-day home health claim payment amount by 60 and then multiply that amount by the days from the CJR admission through April 1 (32 days) to prorate the HHA payment. This proposed prorating method for HHA claims is consistent with how partial episode payments (PEP) are paid for on home health claims.

For IPPS services that extend beyond the episode (for example, readmissions included in the episode definition), we proposed to separately prorate the IPPS claim amount from episode target price and actual episode payment calculations as proposed in section III.C.8. of the proposed rule, called the normal MS–DRG payment amount for purposes of this final rule. The normal MS–DRG payment amount would be pro-rated based on the geometric mean length of stay, comparable to the calculation under the IPPS PAC transfer policy at § 412.4(f) and as published on an annual basis in Table 5 of the IPPS/LTCH PPS Final Rules. Consistent with the IPPS PAC transfer policy, the first day for a subset of MS–DRGs (indicated in Table 5 of the IPPS/LTCH PPS Final Rules) would be doubly weighted to count as 2 days to account for likely higher hospital costs incurred at the beginning of an admission. If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment would be fully allocated to the episode. If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount would be allocated to the episode based on the number of inpatient days that fall within the episode. If the full amount is not allocated to the episode, any remainder amount would be allocated to the 30 day post-episode payment calculation discussed in section III.C.8.d. of the proposed rule. The proposed approach for prorating the normal MS–DRG payment amount is consistent with the IPPS transfer per diem methodology.

The following is an example of prorating for IPPS services that extend beyond the episode. If beneficiary has a readmission for MS–DRG 493—lower extremity and humerus procedures except hip, foot, and femur, with complications—into an IPPS hospital on the 89th day after discharge from a CJR anchor hospitalization, and is subsequently discharged after a length of stay of 5 days, Medicare payment for this readmission would be prorated for inclusion in the episode. Based on Table 5 of the IPPS/LTCH PPS Final Rule for FY 2015, the geometric mean for MS–DRG 493 is 4 days, and this MS–DRG is indicated for double-weighting the first day for proration. This readmission has only 2 days that falls within the episode, which is less than the MS–DRG 493 geometric mean of 4 days. Therefore, the normal MS–DRG payment amount associated with this readmission would be divided by 4 (the geometric mean) and multiplied by 3 (the first day is counted as 2 days, and the second day contributes the third day), and the resulting amount is attributed to the episode. The remainder one-fourth would be captured in the post-episode spending calculation discussed in section III.C.8. of the proposed rule. If the readmission occurred on the 85th day after discharge from the CJR anchor hospitalization, and the length of stay was 7 days, the normal MS–DRG payment amount for the admission would be included in the episode without proration because length of stay for the readmission falling within the episode (6 days) is greater than or equal to the geometric mean (4 days) for the MS–DRG.

We considered an alternative option of including the full Medicare payment for all services that start during the episode, even if those services did not conclude until after the episode ended, in calculating episode target prices and actual payments. Previous research on bundled payments for episodes of PAC services noted that including the full payment for any claim initiated during the fixed episode period of time will capture continued service use. However, prorating only captures a portion of actual service use (and payments) within the bundle.[20] As discussed in section III.B. of this final rule, the CJR model proposed an episode length that extends 90 days post-discharge, and Table 5 in section III.B.3.c. of the proposed rule demonstrates that the average length of stay in PAC during a 90-day episode with a MS–DRG 470 anchor hospitalization is 47.3 days. Therefore, the length of the episode under CJR (90 days) should be sufficient to capture the vast majority of service use within the episode, even if payments for some services that extend beyond the episode duration are prorated and only partly attributed to the episode.

The following is a summary of comments received and our responses.

*Comment:* Several commenters supported the pro-rating of payments for services that extend beyond the episode. They agreed that pro-rating would help ensure target prices and actual episode payments reflect services that were furnished during the episode. A commenter requested clarification on how payments for IRFs would be pro-rated. Another commenter stated that the first day for pro-rated surgical MS–DRGs paid under IPPS should be weighted by more than the two-times weight proposed; the commenter believed that a multiplier of up to 4.5 would more accurately describe hospitals' costs for the first day of surgical inpatient admissions reimbursed under Medicare IPPS.

[20] *http://aspe.hhs.gov/health/reports/09/pacepifinal/report.pdf.*

*Response:* We appreciate commenters' support for pro-rating payments for services that extend beyond the episode. As described in section III.C.3.b of this final, IRF payments will be pro-rated based on the percentage of actual length of stay (in days) that falls within the episode window. Prorated IRF payments would also be similarly allocated to the 30 day post episode payment calculation in section III.C.8.d. of this final rule.

We agree that costs for inpatient stays may not be equal for each day of an inpatient admission, and the distribution of costs may differ between surgical and non-surgical inpatient stays. We acknowledge there may be different methodologies to calculate how much more costs are incurred on the first day of a stay. However, we will maintain consistency with the IPPS per diem transfer policy that uses a two-times weight for the first day for a subset of MS–DRGs as described in § 412.4(f) and published on an annual basis in Table 5 of the IPPS/LTCH PPS Final Rules. We also note that many surgical readmissions are excluded from the episode definition described in section III.B. of this final rule, which should mitigate the impact of this prorating approach on surgical readmissions that extend beyond the episode.

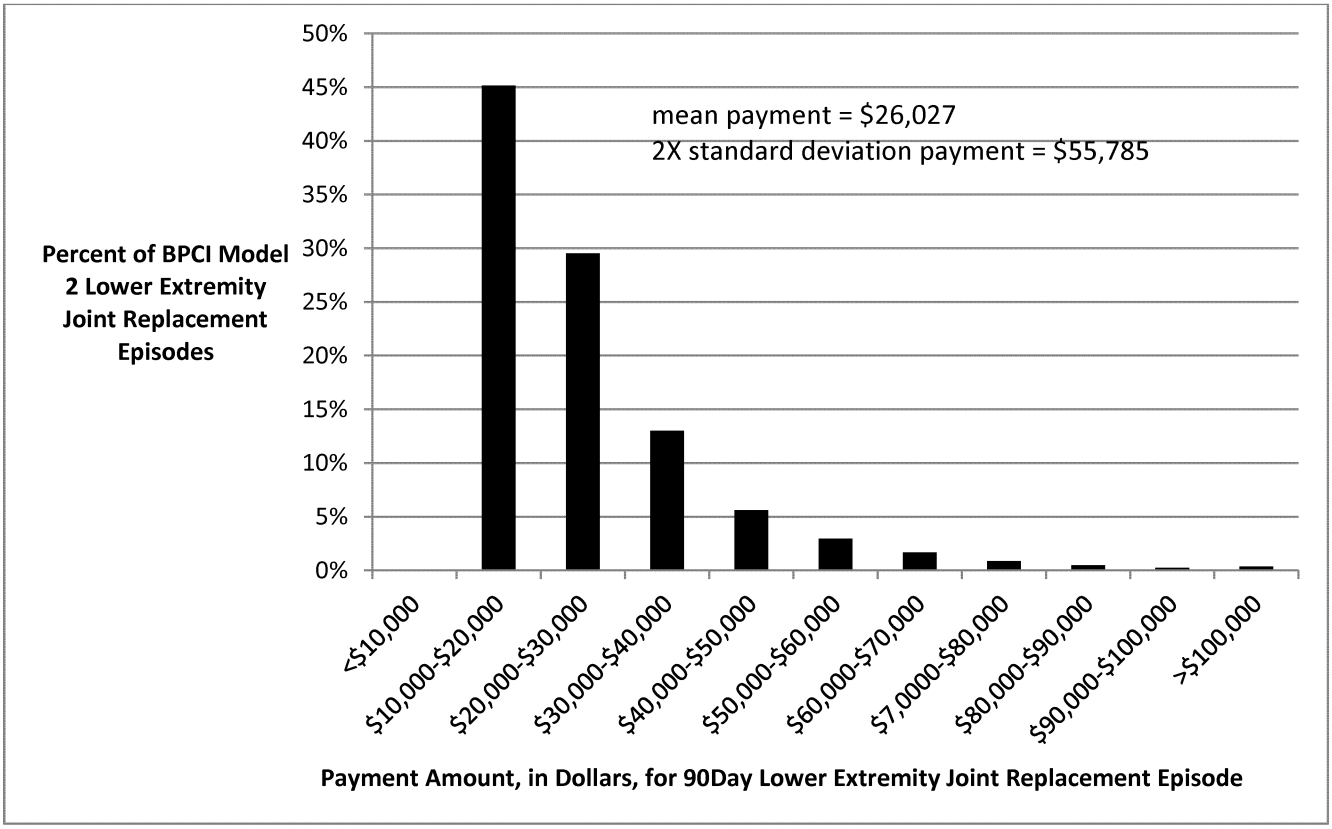
*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to prorate payments for services that extend beyond the episode when calculating actual episode payments, setting episode target prices, and calculating reconciliation and repayment amounts.

c. Pricing Adjustment for High Payment Episodes

Given the broad proposed LEJR episode definition and 90-day post-discharge episode duration proposed for CJR, we want to ensure that hospitals have some protection from the variable repayment risk for especially high payment episodes, where the clinical scenarios for these cases each year may differ significantly and unpredictably. We did not believe the opportunity for a hospital's systematic care redesign of LEJR episodes has significant potential to impact the clinical course of these extremely disparate high payment cases.

The BPCI Model 2 uses a generally similar episode definition as proposed for CJR and the vast majority of BPCI episodes being tested for LEJR are 90 days in duration following discharge from the anchor hospitalization. Similarly in the proposed rule, we stated our belief that the distribution of 90-day LEJR episode payment amounts utilizing the BPCI Model 2 episode definition as displayed in Figure 2 provides information that is relevant to policy development regarding CJR episodes.

**FIGURE 2: ESTIMATED NATIONAL DISTRIBUTION OF LEJR 90 day EPISODE PAYMENT AMOUNTS[1 2]**




Source: Medicare FFS Part A and B claims from October 1, 2013 to September 30, 2014.

1. Assumes no changes in volume or utilization pattern.

2. Payment reflects wage index removal.

As displayed, the mean episode payment amount is approximately $26,000. Five percent of all episodes are paid at two standard deviations above the mean payment or greater, an amount that is slightly more than 2 times the mean episode payment amount. While these high payment cases are relatively uncommon, we stated in the proposed rule our belief that incorporation of the full Medicare payment amount for such high payment episodes in setting the target price and correspondingly in Medicare's aggregate actual episode payment that is compared to the target price for the episode may lead in some cases to excessive hospital responsibility for these episode expenditures. This may be especially true when hospital responsibility for repayment of excess episode spending is introduced in performance year 2. The hospital may have limited ability to moderate spending for these high payment cases. Our proposal to exclude IPPS new technology add-on payments and separate payment for clotting factors for the anchor hospitalization from the episode definition limits excessive financial responsibility under this model of extremely high inpatient payment cases that could result from costly hospital care furnished during the anchor hospitalization. However, in the proposed rule we stated our belief that an additional pricing adjustment in setting episode target prices and calculating actual episode payments is necessary to mitigate the hospital responsibility for the actual episode payments for high episode payment cases resulting from very high Medicare spending within the episode during the period after discharge from the anchor hospitalization, including for PAC, related hospital readmissions, and other items and services related to the LEJR episode.

Thus, in order to limit the hospital's responsibility for the previously stated high episode payment cases, we proposed to utilize a pricing adjustment for high payment episodes that would incorporate a high payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices.

Specifically, when setting target prices, we would first identify for each anchor MS–DRG in each region (discussed further in section III.C.4. of this final rule) the episode payment amount that is two standard deviations above the mean payment in the historical dataset used (discussed further in section III.C.4. of the proposed rule). Any such identified episode would have its payment capped at the MS–DRG anchor and region-specific value that is two standard deviations above the mean, which would be the ceiling for purposes for calculating target prices. We note that the calculation of the historical episode high payment ceiling for each region and MS–DRG anchor would be performed after other steps, including removal of effects of special payment provisions and others described in section III.C.4.c. of this final rule.

When comparing actual episode payments during the performance year to the target prices, episode payments for episodes in the performance year would also be capped at two standard deviations above the mean. The high episode payment ceiling for episodes in a given performance year would be calculated based on MS–DRG anchor-specific episodes in each region. We discuss further how the high episode payment ceiling would be applied when comparing episode payments during the performance year to target prices in section III.C.6. of this final rule.

While this approach generally lowers the target price slightly, it provides a basis for reducing the hospital's responsibility for actual episode spending for high episode payment cases during the model performance years. When performing the reconciliation for a given performance year of the model, we would array the actual episode payment amounts for all episodes being tested within a single region, and identify the regional actual episode payment ceiling at two standard deviations above the regional mean actual episode payment amount. If the actual payment for a hospital's episode exceeds this regional ceiling, we would set the actual episode payment amount to equal the regional ceiling amount, rather than the actual amount paid by Medicare, when comparing a hospital's episode spending to the target price. Thus, a hospital would not be responsible for any actual episode payment that is greater than the regional ceiling amount for that performance year. We proposed to adopt this policy for all years of the model, regardless of the reconciliation payment opportunity or repayment responsibility in a given performance year, to achieve stability and consistency in the pricing methodology. We stated in the proposed rule our belief that this proposal provides reasonable protection for hospitals from undue financial responsibility for Medicare episode spending related to the variable and unpredictable course of care of some Medicare beneficiaries in CJR episodes, while still fully incentivizing increased efficiencies for approximately the 95 percent of episodes for which we estimate actual episode payments to fall below this ceiling.[21] We sought comment on our proposal to apply a pricing adjustment in setting target prices and reconciling actual episode payments for high payment episodes.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters supported the proposal for a high episode payment ceiling at two standard deviations above the mean episode payment amount in calculating the target price and in comparing actual episode payments during the performance year to the target prices. They agreed that such a ceiling would help limit financial exposure to participant hospitals from outlier episodes. Some commenters requested the option of choosing specific risk tracks as provided under BPCI (for example, high episode payment ceiling at 75th, 95th, or 99th percentile).

*Response:* We appreciate commenters' support for a high episode payment ceiling. We acknowledge that BPCI offers different risk tracks with different outlier protection features from which participants can choose, and that we did not propose to provide CJR participant hospitals with choice of risk tracks or outlier protection policy. However, with the blending of regional and hospital-specific historical episode expenditure data that we are finalizing in section III.C.4.b.(5) of this final rule to calculate target prices, applying different risk tracks or outlier protection policies to different hospitals would distort target price calculations; this is not an issue in BPCI because target prices are calculated using only hospital-specific historical episode expenditure data. Additionally, we continue to believe that setting a high episode payment ceiling at two standard deviations above the mean episode payment amount, along with the phasing in of responsibility for hospital repayment in performance year 1 as discussed in section III.C.2 of this final rule, will be sufficient to limit financial exposure due to outlier episodes. We will finalize our proposal to use a common outlier policy for all participant hospitals.

*Comment:* Many commenters requested that CMS risk adjust episode spending based on patients' hip fracture status, among other clinical and demographic dimensions.

*Response:* We refer readers to comments and responses to comments

[21] Medicare FFS Parts A and B claims, CJR episodes as proposed, between October 1, 2013 and September 30, 2014.

in section III.C.4.b.(1) of this final rule for further discussion on risk stratification for hip fracture status, and we reference it here because changes to risk stratification would impact how a high payment episode ceiling would function. As discussed in the responses to comments in section III.C.4.b.(1) of this final rule, we will modify our policy in this final rule so as to set different target prices both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. Given this change, we will also modify the proposed approach to apply the high payment episode ceiling. Specifically, instead of calculating and applying high payment episode ceilings for each region and anchor MS–DRG combination, we will now calculate and apply high payment episode ceilings for each region, anchor MS–DRG, and hip fracture status combination.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to apply high episode payment ceilings when calculating actual episode payments, setting episode target prices, and calculating reconciliation and repayment amounts. However, we do note that the approach to calculate and apply the high episode payment ceilings will be adapted to account for the risk stratification based on hip fracture status discussed in section III.C.4.b. of this final rule.

4. Episode Price Setting Methodology

a. Overview

Whether a participant hospital receives reconciliation payments or is made responsible to repay Medicare for the CJR model will depend on the hospital's quality and actual payment performance relative to episode quality and target prices. Quality performance and its tie to payments is further discussed in section III.C.5. of this final rule, and the remainder of this section will discuss the proposed approach to establishing target prices.

We proposed to establish CJR target prices for each participant hospital. For episodes beginning in performance years 1, 3, 4, and 5, a participant hospital would have eight target prices, one for each of the following:

- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the voluntary patient-reported outcome measure proposed in section III.C.5. of the proposed rule.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital successfully submits data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between January 1 and September 30 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 469 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.
- MS–DRG 470 anchored episodes that were initiated between October 1 and December 31 of the performance year, if the participant hospital does not successfully submit data on the proposed voluntary patient-reported outcome measure.

For episodes beginning in performance year 2, a participant hospital would have 16 target prices. These would include the same combinations as for the other 4 performance years, but one set for determining potential reconciliation payments, and the other for determining potential Medicare repayment amounts, as part of the phasing in of two-sided risk discussed later in this section. Further discussion on our proposals for different target prices for MS–DRG 469 versus MS–DRG 470 anchored episodes, for episodes initiated between January 1 and September 30 versus October 1 and December 31, and for participant hospitals that do and do not successfully submit data on the proposed patient-reported outcome measure can be found in sections III.C.4.b. and III.C.5. of the proposed rule.

We intend to calculate and communicate episode target prices to participant hospitals prior to the performance period in which they apply (that is, prior to January 1, 2017, for target prices covering episodes initiated between January 1 and September 30, 2017; prior to October 1, 2017 for target prices covering episodes initiated between October 1 and December 31, 2017). We stated in the proposed rule our belief that prospectively communicating prices to hospitals will help them make any infrastructure, care coordination and delivery, and financial refinements they may deem appropriate to prepare for the new episode target prices.

The proposed approach to setting target prices incorporated the following features:

- Set different target prices for episodes anchored by MS–DRG 469 versus MS–DRG 470 to account for patient and clinical variations that impact hospitals' cost of providing care.
- Use 3 years of historical Medicare payment data grouped into episodes of care according to the episode definition in section III.B. of the proposed rule, hereinafter termed historical CJR episodes. The specific set of 3-historical-years used would be updated every other performance year.
- Apply Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, MPFS, etc.) updates to the historical episode data to ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Because different Medicare payment system updates become effective at two different times of the year, we would calculate separate target prices for episodes initiated between January 1 and September 30 versus October 1 and December 31.
- Blend together hospital-specific and regional historical CJR episode payments, transitioning from primarily provider-specific to completely regional pricing over the course of the 5 performance years, to incentivize both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Regions would be defined as each of the nine U.S. Census divisions.
- Normalize for provider-specific wage adjustment variations in Medicare payment systems when combining provider-specific and regional historical CJR episodes. Wage adjustments would

be reapplied when determining hospital-specific target prices.

• Pool together CJR episodes anchored by MS DRGs 469 and 470 to use a greater historical CJR episode volume and set more stable prices.

• Apply a discount factor to serve as Medicare's portion of reduced expenditures from the CJR episode, with any remaining portion of reduced Medicare spending below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred.

Further discussion on each of the individual features can be found in section III.C.4.b. of this final rule. In section III.C.4.c. of this final rule, we also provide further details on the proposed sequential steps to calculate target prices and how each of the pricing features would fit together.

The following is a summary of the comments received and our responses.

*Comment:* Commenters responded on several of the proposed pricing features, including how quality performance would affect payment, and we refer readers to comments and responses to comments in sections III.C.4.b and III.C.5 for further discussion on changes to how quality would be tied to payment as described in the proposed rule. We reference these comments here because any changes to the proposed episode price setting methodology and link between quality performance and payment would impact the number of target prices for each participant hospital.

*Response:* As further discussed in section III.C.4.b.(1) of this final rule, we are modifying the proposed rule to risk stratify (and set different prices) based on not just different anchor MS–DRGs but also patients' hip fracture status. As discussed in section III.C.4.b.(9) of this final rule, we are modifying our policy in this final rule so as to use lower discount factors for purposes of determining the hospital's responsibility for excess episode spending not only in performance year 2, but also in performance year 3. Additionally, as discussed in section III.C.5 of this final rule, we are modifying the proposed rule so as to provide different levels of quality incentive payments that would modulate participant hospitals' effective target price discount factor based on their quality performance. Because of these changes, each participant hospital in performance years 1, 4, and 5 will have 8 potential target prices for each combination of anchor MS–DRG (469 vs. 470), hip fracture status (with hip fracture vs. no hip fracture), and episode initiation date (between April 1 and September 30 vs. between October 1 and December 31 for performance year 1, and between January 1 and September 30 vs. between October 1 and December 31 for performance years 2 through 5). Each participant hospital in performance years 2 and 3 will have 16 target prices for the same combinations in performance years 1, 4, and 5, but with one group of 8 potential target prices for purposes of calculating reconciliation payments and another group of 8 potential target prices for purposes of determining hospital's responsibility for excess episode spending.

b. Pricing Features

(1) Different Target Prices for Episodes Anchored by MS–DRG 469 Versus MS–DRG 470

For each participant hospital we proposed to establish different target prices for CJR episodes initiated by MS–DRG 469 versus MS–DRG 470. MS–DRGs under the IPPS account for some of the clinical and resource variations that exist and that impact hospitals' cost of providing care. Specifically, MS–DRG 469 is defined to identify, and provide hospitals a higher Medicare payment to reflect the higher hospital costs for, hip and knee procedures with major complications or comorbidities. Therefore, we proposed to risk stratify and calculate separate target prices for each participant hospital for CJR episodes with MS–DRG 469 versus MS–DRG 470 anchor hospitalizations.

We considered risk adjusting the episode target prices by making adjustments or setting different prices based on patient-specific clinical indicators (for example, comorbidities). However, we did not believe there is a sufficiently reliable approach that exists suitable for CJR episodes beyond MS–DRG-specific pricing, and there is no current standard on the best approach. At the time of developing the proposed rule Tennessee, Ohio, and Arkansas are launching multi-payer (including Medicaid and commercial payers, excluding Medicare) bundles and include hip and knee replacement as an episode.[22] [23] [24] These states' hip and knee episode definitions and payment models are consistent with, though not the same as, the proposed CJR episode described in the proposed rule. However, each of these three states uses different risk adjustment factors. This variation across states supported our stated belief in the proposed rule that there is currently no standard risk adjustment approach widely accepted throughout the nation that could be used under CJR, a model that would apply to hospitals across multiple states. Therefore, we did not propose to make risk adjustments based on patient-specific clinical indicators.

We also considered making risk adjustments based on the participant hospital's average Hierarchical Condition Category (HCC) score for patients with anchor CJR hospitalizations. The CMS–HCC risk adjustment model quantifies a beneficiary's risk by examining the beneficiary's demographics and historical claims data and predicting the beneficiary's total expenditures for Medicare Parts A and B in an upcoming year. However, the CMS–HCC risk adjustment model's intended use is to pay Medicare Advantage (MA) plans appropriately for their expected relative costs. For example, MA plans that disproportionately enroll the healthy are paid less than they would have been if they had enrolled beneficiaries with the average risk profile, while MA plans that care for the sickest patients are paid proportionately more than if they had enrolled beneficiaries with the average risk profile. The CMS–HCC risk adjustment model is prospective. It uses demographic information (that is, age, sex, Medicare/Medicaid dual eligibility, disability status) and a profile of major medical conditions in the base year to predict Medicare expenditures in the next year.[25] As previously noted, the CMS–HCC risk adjustment model is used to predict total Medicare expenditures in an upcoming year, and may not be appropriate for use in predicting expenditures over a shorter period of time, such as the CJR episode, and may not be appropriate in instances where its use is focused on LEJRs. Therefore, since we have not evaluated the validity of HCC scores for predicting Medicare expenditures for shorter episodes of care or for specifically LEJR beneficiaries, we did not propose to risk

[22] Tennessee Health Care Innovation Initiative. *http://www.tn.gov/HCFA/strategic.shtml.* Accessed on April 16, 2015.

[23] Ohio Governor''s Office of Health Transformation. Transforming Payment for a Healthier Ohio, June 8, 2014. *http://www.healthtransformation.ohio.gov/LinkClick.aspx?fileticket=TDZUpL4a-SI%3d&tabid=138*, Accessed on April 16, 2014.

[24] Total Joint Replacement Algorithm Summary, Arkansas Health Care Payment Improvement Initiative, November 2012. *http://www.paymentinitiative.org/referenceMaterials/Documents/TJR%20codes.pdf.* Accessed on April 17, 2015.

[25] Pope, C. et al., Evaluation of the CMS–HCC Risk Adjustment Model Final Report. Report to the Centers for Medicare & Medicaid Services under Contract Number HHSM–500–2005–00029I. RTI International. Research Triangle Park, NC. March, 2011.

adjust the target prices using HCC scores for the CJR model.

We also considered risk stratifying or setting different prices for different procedures, such as different prices for hip versus knee replacements, but we did not believe there would be substantial variation in episode payments for these clinical scenarios to warrant different prices or adjustments. Moreover, Medicare IPPS payments, which account for approximately 50 percent [26] of CJR episode expenditures, do not differentiate between hip and knee procedures, mitigating procedure-specific variation for the anchor hospitalization. Furthermore, there are no widely accepted clinical guidelines to suggest that PAC intensity would vary significantly between knee and hip replacements. We sought comment on our proposal to price episodes based on the MS–DRG for the anchor hospitalization, without further risk adjustment.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters stated that proper risk adjustment is necessary for the success of this model, and that anchor MS–DRG-specific pricing can help but is not sufficient on its own. Proper risk adjustment would account for differences in episode spend due to patient variations that are out of providers' control. They stated that MS–DRGs may capture variations within the inpatient setting, but do not reflect patient variations post-discharge. Inappropriate risk adjustment could lead to access issues for higher risk patients and increased volume of LEJR procedures for younger/healthier patients by participant hospitals looking to lower their average episode expenditures.

Most commenters who wrote on the issue suggested risk adjustment or complete exclusion for episodes with hip fractures, partial hip replacements, and emergent (versus non-emergent or elective) procedures. Some commenters provided analysis on hip fractures, in particular, and demonstrated episodes with hip fractures are significantly more expensive than those without hip fractures. Other clinical and demographic dimensions offered for risk adjustment or exclusion include the following: Procedure (total hip [THA] vs. total knee [TKA] vs. partial hip [PHA] vs. ankle vs. limb reattachment); socioeconomic status; patient functional status; age; and comorbidities. Requests from commenters for risk adjustment based on the previously stated dimensions were usually paired with requests to also exclude patients from the CJR model, and we encourage readers to read comments in section III.B.2.a. of this final rule for additional details on the clinical and demographic dimensions requested for risk adjustment or exclusion.

Some commenters who wrote on the issue of risk adjustment disputed CMS' statement in the proposed rule that there is no standard risk adjustment approach widely accepted throughout the nation. They pointed to examples of existing risk adjustment approaches that could be used for CJR episodes, such as Optum's Procedure Episode Grouper (PEG), Truven's Medical Episode Grouper (MEG), Health Care Incentives Improvement Institute's (HCI3) risk adjustment model, CMS's HCCs model, and CMS's risk-adjusted quality/efficiency metric for elective LEJR episodes: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).

*Response:* In response to comments, we undertook further analysis. Our analysis showed that episodes with hip fractures, identified by historical anchor hospitalization claims with an ICD–9–CM hip fracture code as the principal diagnosis, have approximately 70 percent greater historical average episode expenditures than episodes without hip fractures, even for episodes within the same anchor MS–DRG, confirming analyses shared by some commenters that also showed episodes with hip fractures to have significantly greater average expenditures.[27] PHA episodes and emergent episodes had similarly higher historical average expenditures than TKA and THA episodes and non-emergent episodes, respectively. There are clearly patient-specific conditions that lead to significant episode expenditure variations, even within the same MS–DRG.

On the basis of the comments and our further analysis, we agree with commenters that proper risk adjustment is necessary to appropriately incentivize participant hospitals to deliver high quality and efficient care. We acknowledge that a comprehensive risk adjustment methodology beyond just setting different prices by anchor MS–DRGs could more accurately risk adjust episodes for patient-specific clinical and demographic factors that would drive variations in CJR episode expenditures.

We disagree with commenters, though, that there is an already existing, widely accepted risk adjustment methodology for CJR episodes. The HCC model, as discussed earlier in this section, is not designed to predict costs within CJR episodes and may not accurately predict CJR episode expenditures. Commercial claims groupers such as Optum's PEG, Truven's MEG, and HCI3's risk adjustment model utilize different episode definitions from how we will define CJR episodes. Additionally, these commercial groupers have yet to be validated for a Medicare population; we believe there may be a different set of risk factors that predict episode expenditures for Medicare beneficiaries than those used to predict episode expenditures for younger and generally healthier individuals with commercial insurance. We also acknowledge that CMS has designed a risk-adjusted quality/efficiency metric for elective LEJR episodes: Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA). This metric, though, has been developed for a different episode definition; most notably, this risk-adjusted metric excludes emergent episodes while the CJR episode definition does not exclude emergent episodes, as discussed in section III.B. of this final rule.

We do believe that there are opportunities to learn from existing comprehensive risk adjustment models, and we may explore how a comprehensive risk adjustment model such as these may be adapted for the CJR model in the future.

In the meantime, though, we also believe we can improve upon the proposed approach of only setting different target prices by anchor MS–DRG. Specifically, we can account for the impact of hip fracture status (with hip fracture vs. without hip fracture), procedure choice (PHA vs. TKA or THA), and emergence status (emergent vs. non-emergent) on episode expenditures. According to our analysis, though, there was significant correlation between incidence of hip fractures, partial hip procedures, and emergent procedures—94 percent of partial hip replacement episodes and 93 percent of emergent episodes are for patients with hip fractures. Because of the correlation between these three factors, we believe we can account for all three by risk stratifying based on hip fracture status alone. We believe hip fracture status is a more appropriate dimension on which

[26] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

[27] Medicare FFS Parts A and B claims, CJR episodes, as proposed in the proposed rule, between October 2013 and September 2014.

to risk stratify because it reflects patients' clinical status, as opposed to partial hip replacements and emergent procedures which are influenced by providers' care delivery decisions.

In light of the comments and our additional analysis, we will modify our proposed policy to risk stratify, or set different target prices, both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. By adding hip fracture status to our risk stratification approach, we believe we can capture a significant amount of patient-driven episode expenditure variation. Additionally, because of the high correlation between incidence of hip fractures, partial hip procedures, and emergent procedures, we do not believe we need to add any procedure-specific and emergent status factors for risk stratification. We still believe, as stated in the proposed rule that PAC intensity would not vary significantly between TKA and THA for beneficiaries without hip fractures.

We will identify episodes with hip fractures using ICD–9–CM or ICD–10–CM diagnosis codes, where the hip fracture diagnosis is the principal diagnosis on the anchor hospitalization claim for an LEJR procedure. Our goal is to identify those CJR episodes where the primary surgical treatment for the hip fracture is an LEJR procedure furnished during the anchor hospitalization. The historical episodes with hip fracture diagnosis codes on the anchor hospitalization claim will be used to set the hip fracture episode target prices under the CJR model, and episodes during the CJR model with hip fracture diagnosis codes on the anchor hospitalization claim will be reconciled at the hip fracture episode target prices.

In order to develop the initial list of ICD–9–CM hip fracture diagnosis codes used to identify those historical episodes with hip fracture for calculating hip fracture episode target prices, to implement changes to the list to account for the transition to the ICD–10–CM diagnosis code set that will be used to identify episodes during the model performance years that will receive fracture episode target prices, and to make other changes as necessary based on annual ICD–10–CM coding changes or to address issues raised by the public throughout the model performance years, we are implementing the following subregulatory process, which mirrors the subregulatory process we will use for the episode definition exclusions list described in section III.B.2 of this final rule. We will use this process on an annual, or more frequent, basis to update the ICD–CM hip fracture diagnosis code list and to address issues raised by the public.

As part of this process, we will first develop the potential ICD–CM hip fracture diagnosis codes based on our assessment according to the following standards:

- The ICD–CM diagnosis code is sufficiently specific that it represents a bone fracture for which a physician could determine that a hip replacement procedure, either a PHA or a THA, could be the primary surgical treatment.
- The ICD–CM diagnosis code is the primary reason (that is, principal diagnosis code) for the anchor hospitalization.

We will then post a list of potential hip fracture diagnosis codes (whether ICD–9–CM diagnosis codes, as necessary to develop initial target prices, or ICD–10–CM diagnosis codes to be utilized during the model performance years) to the CMS Web site at *http://innovation.cms.gov/initiatives/cjr/* to allow for public input on our planned application of these standards, and then we will adopt the ICD–CM hip fracture diagnosis code list with posting to the CMS Web site of the final ICD–CM hip fracture diagnosis code list after our consideration of the public input.

With public release of this final rule, we are initiating this subregulatory process to develop a final ICD–9–CM hip fracture diagnosis code list that will be used to identify historical anchor hospitalizations for beneficiaries with hip fracture for purposes of determining episode spending in the historical period and developing initial target prices for the model. The potential ICD–9–CM hip fracture diagnosis code list is posted on the CJR Web site at *http://innovation.cms.gov/initiatives/cjr/*. Given our objective to quickly develop target prices and provide them to participant hospitals in the timeframe described in section III.C.4. of this final rule, we will allow for public input on this list for 14 days after the public release of this final rule. Public comments will be submitted via an email address posted on the CJR Web site along with the list of potential ICD–9–CM hip fracture diagnosis codes previously referenced. We will consider the public's input and then, after consideration, we will post the final ICD–9–CM hip fracture diagnosis code list to the CMS Web site. This list will be used to calculate the first set of target prices communicated to participant hospitals. Within 30 days of public release of the final rule, we will again initiate this subregulatory process to identify ICD–10–CM hip fracture diagnosis codes by posting the potential ICD–10–CM hip fracture diagnosis code list on the CMS Web site and seeking public input, so we can provide in a timely manner the final list of ICD–10–CM hip fracture diagnosis codes prior the beginning of the first model performance year.

*Final Decision:* After consideration of the public comments we received, we are modifying the proposed rule to risk stratify (and set different target prices) based on not just different anchor MS–DRGs but also patients' hip fracture status. We will identify episodes with hip fractures using ICD–9–CM or ICD–10–CM diagnosis codes in the principal position on the claim for the anchor hospitalization. We are instituting a subregulatory process in order to allow for public comment and to finalize the ICD–9–CM and ICD–10–CM diagnosis codes to be used in identifying hip fracture cases in the CJR model, which we are initiating as of the public release of this final rule. We refer readers to the list of ICD–9–CM diagnosis codes posted on the CJR model Web site at *http://innovation.cms.gov/initiatives/cjr/*.

This policy is codified at § 510.300(a).

(2) Three Years of Historical Data

We proposed to use 3 years of historical CJR episodes for calculating CJR target prices. The set of 3-historical-years used would be updated every other year. Specifically—

- Performance years 1 and 2 would use historical CJR episodes that started between January 1, 2012 and December 31, 2014;
- Performance years 3 and 4 would use historical episodes that started between January 1, 2014 and December 31, 2016; and
- Performance year 5 would use episodes that started between January 1, 2016 and December 31, 2018.

We considered using fewer than 3 years of historical CJR episode data, but we are concerned with having sufficient historical episode volume to reliably calculate target prices. We also considered not updating the historical episode data for the duration of the model. However, we stated in the proposed rule our belief that hospitals' target prices should be regularly updated on a predictable basis to use the most recent available claims data, consistent with the regular updates to Medicare's payment systems, to account for actual changes in utilization. We are not proposing to update the data annually, given the uncertainty in pricing this could introduce for participant hospitals. We also note that the effects of updating hospital-specific data on the target price could be limited

as the regional contribution to the target price grows, moving to two-thirds in performance year 3 when the first historical episode data update would occur.

The following is a summary of the comments received and our responses.

*Comment:* Commenters generally supported using historical expenditures to set target prices. Several commenters expressed concern that updating the 3 years of historical CJR episode data every other year would effectively make participant hospitals compete against themselves without consideration of whether they are already efficient. Some of these commenters cited that BPCI does not update its historical data for the entirety of the BPCI model, and some other commenters noted that Medicare Shared Savings Program resets its historical benchmark every three years with each new participation agreement. There were also a few commenters that supported updating the 3 years of historical CJR episode data every 2 years because it was better than doing so every year.

Some commenters also stated that if we do update the historical data, we should include previous reconciliation payments and repayments to Medicare for the participant hospitals. We refer readers to comments and responses to comments in section III.C.3 of this final rule for further discussion on this comment.

Some commenters proposed alternative approaches to getting to target prices other than using and updating historical data. Some commenters suggested using a negotiations/bidding process approach to get to target prices; Medicare would negotiate with or request bids from providers for providing services covered under the CJR episode definition. Some other commenters suggested applying some sort of inflation factor, such as a CMS market basket update, for future years of the model instead of updating the 3 years of historical CJR episode data. These alternatives to using and updating the historical CJR episode data would help prevent a participant hospital from competing against its historical self, even if it is already efficient, in order to qualify for reconciliation payments.

*Response:* We appreciate commenters' support for using historical expenditures to set target prices. We acknowledge that BPCI does not update participants' historical data and Medicare Shared Savings Program does not reset participating entities' benchmark for 3 years (until the beginning of a new agreement period). However, these programs employ alternative mechanisms to account for recent national trends reflecting changes in industry wide practice patterns. BPCI, for example, retrospectively applies a national trend factor to trend forward historical episode expenditure data and capture changes in nationwide practice patterns between the time period used in the historical data and the performance period. BPCI participants are not penalized or rewarded for mirroring nationwide practice pattern trends. In BPCI, however, participants' target prices are determined retrospectively after the close of each performance period. We intend to calculate and communicate target prices prior to the start of each performance year, as discussed in section III.C.4.a of this final rule, so we cannot utilize the retrospective national trend factor approach as used in BPCI.

Instead, we proposed to capture changes in nationwide practice patterns by updating every other year the historical CJR episode data used to set target prices. We recognize that this approach of updating the historical episode data every other year effectively assumes a zero percent change in utilization between the latest year of historical episode data and the performance year. We believe this can be a valid estimate for a few years (for example, 2014 as the latest year of historical episode data for 2017 target prices; update historical episode data for 2018 target prices), but it is less likely to hold true for longer periods of time (for example, 2014 as the latest year of historical episode data for 2020 target prices; no update to historical episode data). Therefore, we believe updating the historical episode data is necessary. While updating the historical episode data more frequently (that is, every year, instead of every other year) would lessen our reliance on an assumption of zero percent utilization change, doing so may exacerbate commenters' concerns that already efficient hospitals would have to compete against themselves, as discussed further later in this section.

We appreciate commenters' concerns that it may be unsustainable for already efficient participant hospitals to continuously improve, and that participant hospitals may undertake activities that promote care coordination and improved quality of care but are not directly reimbursed under applicable Medicare FFS payment systems. If we were using 100 percent hospital-specific pricing, updating the historical data used to set target prices without including reconciliation payments would create a lower and harder to achieve target price for participant hospitals that previously increased efficiency. As discussed in section III.C.3 of this final rule, we may revisit in future rulemaking our decision to exclude reconciliation payments and repayment amounts when updating the set of historical years used to set target prices. Additionally, as we transition to regional pricing over the course of the model, participant hospitals will no longer compete against their historical selves but rather strive to outperform their regional peers. Under regional pricing, an already efficient hospital may be able to achieve actual episode expenditures below the regional target price without having to become even more efficient. By performance year 3, when the first update to historical episode data would occur, the majority of the target price would be based on the regional component, not the hospital-specific component, as described in section III.C.4.b.(5) of this final rule.

We appreciate commenters' suggestions on using alternative approaches to setting target prices. We may consider such approaches for future model tests.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal, without modification, to use three years of historical expenditures, updated every other year, to set target prices.

(3) Trending of Historical Data to the Most Recent Year of the Three

We acknowledge that some payment variation may exist in the 3 years of historical CJR episodes due to updates to Medicare payment systems (for example, IPPS, OPPS, IRF PPS, SNF PPS, etc.) and national changes in utilization patterns. Episodes in the third of the 3-historical-years may have higher average payments than those from the earlier 2 years because of Medicare payment rate increases over the course of the 3-historical-years. We do not intend to have CJR incentives be affected by Medicare payment system rate changes that are beyond hospitals' control. In addition to the changes in Medicare payment systems, average episode payments may change year over year due to national trends reflecting changes in industry-wide practice patterns. For example, readmissions for all patients, including those in CJR episodes, may decrease nationally due to improved industry-wide surgical protocols that reduce the chance of infections. We do not intend to provide reconciliation payments to (or require repayments from) hospitals for achieving lower (or higher) Medicare expenditures solely because they followed national changes in practice

patterns. Instead, we aim to incentivize hospitals based on their hospital-specific inpatient and PAC delivery practices for LEJR episodes.

To mitigate the effects of Medicare payment system updates and changes in national utilization practice patterns within the 3 years of historical CJR episodes, we proposed to apply a national trend factor to each of the years of historical episode payments. Specifically, we proposed to inflate the 2 oldest years of historical episode payments to the most recent year of the 3-historical-years described in section III.C.4.b.(2) of the proposed rule. We proposed to trend forward each of the 2 oldest years using the changes in the national average CJR episode payments. We also proposed to apply separate national trend factors for episodes anchored by MS–DRG 469 versus MS–DRG 470 to capture any MS–DRG-specific payment system updates or national utilization pattern changes. For example, when using CY 2012–2014 historical episode data to establish target prices for performance years 1 and 2, under our proposal we would calculate a national average MS–DRG 470 anchored episode payment for each of the 3-historical-years. The ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2012 would be used to trend 2012 MS–DRG 470 anchored episode payments to CY 2014. Similarly, the ratio of the national average MS–DRG 470 anchored episode payment for CY 2014 to that of CY 2013 would be used to trend 2013 episode payments to CY 2014. The previously stated process would be repeated for MS–DRG 469 anchored episodes. Trending CY 2012 and CY 2013 data to CY 2014 would capture updates in Medicare payment systems as well as national utilization pattern changes that may have occurred.

We considered adjusting for regional trends in utilization, as opposed to national trends. However, we stated in the proposed rule our belief that any Medicare payment system updates and significant changes in utilization practice patterns would not be region-specific but rather be reflected nationally.

We sought comment on our proposal to nationally trend historical data to the most recent year of the 3 being used to set the target prices.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters supported the use of national trends for trending historical data to the most recent of the 3 being used to set the target prices. Some commenters suggested blending regional, instead of national, trends to be consistent with how target prices will be blended, as discussed in section III.C.4.b.(5) of this final rule. Some commenters inquired how trending historical data would capture changes in Medicare FFS fee schedules.

*Response:* We appreciate commenters' support for the use of national trends for trending historical data. This trending of historical data to the most recent of the 3 being used to set target prices would capture both Medicare FFS fee schedule and practice pattern changes. Medicare FFS fee schedule changes would be captured in the trend factor calculations; for example, if Medicare FFS fee schedules change so as to increase overall payments by 4 percent between the oldest and most recent year of historical episode data, the national trend factor applied to the oldest year of historical episode data would be 1.04 (assuming no change in utilization patterns). Medicare FFS fee schedule changes apply across the nation, and we believe that major changes to practice patterns would be nationwide and not constrained to any one region.

*Comment:* Many commenters requested for risk adjustment based on patients' hip fracture status, among other clinical and demographic dimensions.

*Response:* We refer readers to comments and responses to comments in section III.C.4.b.(1) of this final rule for further discussion on risk stratification, and we reference it here because changes to risk stratification would impact how we would trend historical data to the most recent year of the three being used. As discussed in the responses to comments in section III.C.4.b.(1) of this final rule, we will modify our proposal so as to set different target prices both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. Given this change, we must also modify the proposed approach to apply national trend factor. Specifically, instead of calculating different national trend factors just for anchor MS–DRGs 469 vs. 470, we will calculate different national trend factors for each combination of anchor MS–DRG (469 vs. 470) and hip fracture status (with hip fracture vs. without hip fracture) using the methodology we proposed.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to trend historical data to the most recent of the 3 being used to set target prices, though instead of calculating different national trend factors just for anchor MS–DRGs 469 vs. 470, we will calculate different national trend factors for each combination of anchor MS–DRG (469 vs. 470) and hip fracture status (with hip fracture vs. without hip fracture).

(4) Update Historical Episode Payments for Ongoing Payment System Updates

We proposed to prospectively update historical CJR episode payments to account for ongoing Medicare payment system (for example, IPPS, OPPS, IRF PPS, SNF, MPFS, etc.) updates to the historical episode data and ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control. Medicare payment systems do not update their rates at the same time during the year. For example, IPPS, the IRF PPS, and the SNF payment system apply annual updates to their rates effective October 1, while the hospital OPPS) and MPFS apply annual updates effective January 1. To ensure we appropriately account for the different Medicare payment system updates that go into effect on January 1 and October 1, we proposed to update historical episode payments for Medicare payment system updates and calculate target prices separately for episodes initiated between January 1 and September 30 versus October 1 and December 31 of each performance year. The target price in effect as of the day the episode is initiated would be the target price for the whole episode. Note that in performance year 5, the second set of target prices would be for episodes that start and end between and including October 1 and December 31 because the fifth performance period of the CJR model would end on December 31, 2020. Additionally, a target price for a given performance year may apply to episodes included in another performance year. For example, an episode initiated in November 2016, and ending in February 2017 would have a target price based on the second set of 2016 target prices (for episodes initiated between October 1 and December 31, 2016), and it would be captured in the CY 2017 performance year (performance year 2) because it ended between January 1 and December 31, 2017. We refer readers to section III.C.3.c. of the proposed rule for further discussion on the definition of performance years.

We proposed to update historical CJR episode payments by applying separate Medicare payment system update factors each January 1 and October 1 to each of the following six components of each hospital's historical CJR payments:

- Inpatient acute.
- Physician.

- IRF.
- SNF.
- HHA.
- Other services.

A different set of update factors would be calculated for January 1 through September 30 versus October 1 through December 31 episodes each performance year. The six update factors for each of the previously stated components would be hospital-specific and would be weighted by the percent of the Medicare payment for which each of the six components accounts in the hospital's historical episodes. The weighted update factors would be applied to historical hospital-specific average payments to incorporate ongoing Medicare payment system updates. A weighted update factor would be calculated by multiplying the component-specific update factor by the percent of the hospital's historical episode payments the component represents, and summing together the results. For example, let us assume 50 percent of a hospital's historical episode payments were for inpatient acute care services, 15 percent for physician services, 35 percent for SNF services, and 0.0 percent for the remaining services. Let us also assume for this example that the update factors for inpatient acute care services, physician services, and SNF services are 1.02, 1.03, and 1.01, respectively. The weighted update factor in this example would be the following: (0.5 * 1.02) + (0.15*1.03) + (0.35*1.01) = 1.018. The hospital in this example would have its historical average episode payments multiplied by 1.018 to incorporate ongoing payment system updates. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of this final rule.

Each of a hospital's six update factors would be based on how inputs have changed in the various Medicare payment systems for the specific hospital. Additional details on these update factors will be discussed later in this section.

Region-specific update factors for each of the previously stated components and weighted update factors would also be calculated in the same manner as the hospital-specific update factors. Instead of using historical episodes attributed to a specific hospital, region-specific update factors would be based on all historical episodes initiated at any CJR eligible hospital within the region. For purposes of this rule, CJR eligible hospitals are defined as hospitals that are paid under IPPS and not a participant in BPCI Model 1 or in the risk-bearing period of Models 2 or 4 for LEJR episodes, regardless of whether or not the MSAs in which the hospitals are located were selected for inclusion in the CJR model. CJR episodes initiated at a CJR eligible hospital will for purposes of this rule be referred to as CJR episodes attributed to that CJR eligible hospital.

We considered an alternative option of trending the historical episode payments forward to the upcoming performance year using ratios of national average episode payment amounts, similar to how we proposed to trend the 2 oldest historical years forward to the latest historical year for historical CJR episode payments in section III.C.4.b.(3) of the proposed rule. Using ratios of national average episode payment amounts would have the advantage of also capturing changes in national utilization patterns in addition to payment system updates between the historical years and the performance year. However, such an approach would need to be done retrospectively, after average episode payments can be calculated for the performance year, because it would rely on the payments actually incurred in the performance period, data that would be not be available before the performance period. While the proposed approach of using component-specific weighted update factors may be more complicated than the previously stated alternative to use ratios of national average episode payment amounts, we stated in the proposed rule our belief that the additional complication is outweighed by the value to hospitals of knowing target prices before the start of an episode for which the target price would apply. We sought comment on this proposed approach of updating historical episode payments for ongoing Medicare payment system changes.

We did not propose to separately and prospectively apply an adjustment to account for changes in national utilization patterns between the historical and performance years. If a prospective adjustment factor for national utilization pattern changes were applied, it may only be meaningful in performance years 2 and 4, when the historical data used to calculate target prices would not be updated, but another year of historical data would be available. In any of the other 3 performance years, the latest available historical year of data would already be incorporated into the target prices. Given that we proposed to refresh the historical data used to calculate target prices every 2 years, we did not believe an additional adjustment factor to account for national practice pattern changes is necessary to appropriately incentivize participant hospitals to improve quality of care and reduce episode payments.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters noted that the Medicare payment system update factors were complicated to calculate. Some commenters supported the use of calculating Medicare payment system update factors at the hospital-specific and regional levels to reflect practice pattern variations, while some others proposed using national update factors to incentivize reduction in medically unnecessary and/or inappropriate practice pattern variations.

A couple of commenters also inquired whether the Medicare payment system update factors accounted for changes Medicare FFS payment system changes. A commenter requested we freeze MS–DRG weights for MS–DRGs 469 and 470 if the weights decrease in any given year as part of the annual Medicare FFS IPPS payment system updates.

*Response:* We acknowledge that the Medicare payment system update factor calculations are complex, but we believe the complexity is necessary to account for Medicare FFS payment system changes. We will use these payment system update factors to ensure that we incentivize hospitals based on utilization and practice patterns, not Medicare payment system rate changes. While changes to Medicare FFS rates for individual services would be applicable nationwide, the relative composition of each service in historical episodes will likely vary by hospital and region. Calculating payment system update factors at the hospital-specific and regional levels will more accurately capture the effects of payment system changes.

We also note that we are finalizing a modification to the equations used to calculate update factors for those payment systems that apply annual updates to their rates effective October 1 of each year. In lieu of calculating the update factors for inpatient acute, SNF, and IRF services using the values applicable at the end of latest historical year used to calculate target prices, we will use a blend of the values applicable during the latest historical year. Such a change will account for the payment systems that update payment rates on a fiscal year cycle, ensure we are calculating update factors based on the payment rates that apply to a given period to the extent feasible, and result in more accurate target price calculations. We reflect this change in the sections III.C.4.b.(4)(a),

III.C.4.b.(4)(c), and III.C.4.b.(4)(d) of this final rule

We believe freezing MS–DRG weights would run counter to our objective to accurately account for the effects of Medicare FFS payment system changes. If we freeze MS–DRG weights and the weights decrease, we may inappropriately overestimate target prices.

*Comment:* Some commenters requested to have a single set of target prices for the entire calendar year, as opposed to two different sets of target prices that would account for intra-year Medicare FFS payment systems updates: one set for January 1 through September 30, and a second set for October 1 through December 31. These commenters stated that a single target price for the entire year may be easier to communicate to participant hospitals, and that the effect of mid-calendar year changes in Medicare FFS (for example, October 1 IPPS changes) could be estimated and reconciled against a single set of target prices for the entire calendar year.

*Response:* We appreciate commenters' desire for simplicity. However, we would not know the extent of October 1 Medicare FFS payment system updates prior to January of the same year. Additionally, the October update includes payment system updates for IPPS, which accounts for the plurality of historical CJR episode expenditures. Without knowing the magnitude of Medicare FFS payment system updates, we do not believe we could reliably calculate target prices. Any estimate would likely require corrections after the end of the performance year, rendering the initial target price unreliable and unrepresentative of the target price used for reconciliation.

*Comment:* Several commenters recommended that we modify the definition of 'CJR eligible hospitals,' the term used to identify hospitals included in calculations for the regional component of target prices (discussed further in section III.C.4.b.(5) of this final rule), to not exclude hospitals that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes. They recommended that some regions may have a greater proportion of these BPCI participants, and excluding them from the calculations for the regional component of target prices would not accurately reflect the region's historical expenditures. Additionally, with fewer hospitals included, the region component of target prices would be more significantly impacted by the performance of just CJR participant hospitals.

*Response:* We agree with commenters' arguments to include hospitals that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes when calculating the regional component of CJR target prices. Including these BPCI hospitals would more accurately reflect the region's historical expenditures, independent of the level of BPCI participation in the region. Therefore, we are not finalizing our proposal to exclude these hospitals from the regional calculation. We will modify the definition of ''CJR eligible hospitals'' to include these BPCI hospitals so that their data is included in the regional component of target prices. We will treat these BPCI participants as though they were any other non-BPCI-participating hospital—we would not apply the BPCI discount factor to claims payments nor include BPCI reconciliation or repayments for these BPCI hospitals. We do not intend to reduce target prices for participant hospitals just because they are located in a region with greater BPCI participation; instead, we want to ensure that we are calculating a representative regional component for target prices. In order to reduce potential confusion, we will also rename ''CJR eligible hospitals'' to be ''CJR regional hospitals''.

We also clarify that BPCI LEJR episodes will be included in the historical data used to calculate the hospital-specific component of target prices. There may be some CJR participant hospitals who were previously participants in BPCI Model 2; there may be some BPCI Model 2 episodes in the historical data initiated by PGPs for which the LEJR procedure took place at the CJR participant hospital; or there may be some BPCI Model 3 episodes in the historical data for which the LEJR procedure took place at the CJR participant hospital. Including the BPCI LEJR episodes from the historical data used to calculate the hospital-specific component of target prices would parallel the previously discussed approach to include BPCI LEJR episodes in the regional component of target prices. Again, as previously discussed for the regional component of target prices, we would not apply the BPCI discount factor to claim payments nor include BPCI reconciliation or repayments for the hospital-specific component of target prices.

*Final Decision:* After consideration of the public comments we received, we are modifying our proposal to update historical episode payments for ongoing payment system updates so as to include in the definition of ''CJR eligible hospitals'' that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes, and rename ''CJR eligible hospitals'' to be ''CJR regional hospitals.'' We are also finalizing a modification to how we calculate update factors to more accurately capture payment system rate changes throughout the calendar year for inpatient acute, IRF, and SNF services. The modification is reflected in III.C.4.b.(4)(a), III.C.4.b.(4)(c), and III.C.4.b.(4)(d) of this final rule.

(a) Inpatient Acute Services Update Factor

The proposed inpatient acute services update factor would apply to payments for services included in the episode paid under the IPPS. This would include payments for the CJR anchor hospitalization and related readmissions at hospitals paid under IPPS, but not payments for related readmissions at CAHs during the episode window. Payments for related readmissions at CAHs would be captured under the update factor for other services in section III.C.4.b.(4)(f) of the proposed rule.

The update factor applied to the inpatient acute services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare IPPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CJR. We proposed to use changes in the following IPPS inputs to calculate the inpatient acute services update factor: IPPS base rate and average of MS–DRG weights, as defined in the IPPS/LTCH Final Rules for the relevant years. The average MS–DRG weight would be specific to each participant hospital and region to account for hospital and region-specific inpatient acute service utilization patterns. Hospital-specific and region-specific average MS–DRG weights would be calculated by averaging the MS–DRG weight for all the IPPS MS–DRGs included in the historical episodes attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively; including MS–DRGs for anchor admissions as well as those for subsequent readmissions that fall within the episode definition. Expressed as a ratio, the inpatient acute services adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.

• The denominator is based on a blend of values applicable in the latest of the 3 historical years used in the target price (TP) calculations, weighted to account for the values applicable prior to October 1, and values applicable starting October 1 when IPPS updates for the new fiscal year are in effect. Note that this weighting incorporates a modification to our proposed methodology for calculating update factors, as previously discussed in section III.C.4.(b)(4) of this final rule.

Therefore, the inpatient acute services update factor formula is shown as—

$$\frac{\text{Base Rate}_{PP} * \text{average MSDRG weight}_{PP}}{\text{Base Rate}_{TP} * \text{average MSDRG weight}_{TP}}$$

(b) Physician Services Update Factor

The proposed physician services update factor would apply to payments for services included in the episode paid under the MPFS for physician services. We proposed to use changes in the following MPFS inputs to calculate the physician services update factor of each participant hospital and region's historical average episode payments: RVUs; work, practice expense, and malpractice (MP) liability geographic practice cost indices (GPCIs); and national conversion factor, as defined in the MPFS Final Rule for the relevant years. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated to account for hospital and region-specific physician service utilization patterns. Hospital-specific and region-specific RVU-weighted GPCIs would be calculated by taking the proportion of RVUs for work, practice expense, and MP liability for physician services included in the historical episodes and attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively, and multiplying each proportion by the relevant GPCI.

Expressed as a ratio, the physician services update factor would equal the following:

• The numerator is based on GPCI values applicable for the upcoming performance period (PP) for which a target price is being calculated.

• The denominator is based on GPCI values applicable at the end of the latest of the 3 historical years used in the target price (TP) calculations.

Therefore, the proposed physician services update factor formula is shown as—

$$\frac{\text{RVU} - \text{weighted GPCI}_{PP} * \text{Conversion factor}_{PP}}{\text{RVU} - \text{weighted GPCI}_{TP} * \text{Conversion factor}_{TP}}$$

(c) IRF Services Update Factor

The proposed IRF services update factor applies to payments for services included in the episode paid under the Medicare inpatient rehabilitation facility prospective payment system (IRF PPS). We proposed to use changes in the IRF Standard Payment Conversion Factor, an input for the IRF PPS and defined in the IRF PPS Final Rule for the relevant years, to update Medicare payments for IRF services provided in the episode. The IRF Standard Payment Conversion Factor is the same for all IRFs and IRF services, so there is no need to account for any hospital-specific or region-specific IRF utilization patterns; each participant hospital and region would use the same IRF services update factor.

Expressed as a ratio, the IRF PPS update factor would equal the following:

• The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.

• The denominator is based on a blend of values applicable in the latest of the 3 historical years used in the target price (TP) calculations, weighted to account for the values applicable prior to October 1, and values applicable starting October 1 when IRF PPS updates for the new fiscal year are in effect. Note that this weighting incorporates a modification to our proposed methodology for calculating update factors, as previously discussed in section III.C.4.(b)(4) of this final rule.

Therefore, the IRF services update factor formula is shown as—

$$\frac{\text{IRF Standard Payment Conversion factor}_{PP}}{\text{IRF Standard Payment Conversion factor}_{TP}}$$

(d) SNF Services Update Factor

The proposed SNF services update factor would apply to payments for services included in the episode and paid under the SNF PPS, including payments for SNF swing bed services. The update factor applied to the SNF services component of each participant hospital and region's historical average episode payments would be based on how average Resource Utilization Group (RUG–IV) Case-Mix Adjusted Federal Rates for the Medicare SNF PPS (defined in the SNF PPS Final Rule) have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CJR. The average RUG–IV Case-Mix Adjusted Federal Rates would be specific to each participant hospital and region to account for hospital and region-specific SNF service utilization patterns. Hospital-specific and region-specific average RUG–IV Case-Mix Adjusted Federal Rates would be calculated by averaging the RUG–IV Case-Mix Adjusted Federal Rates for all SNF services included in the historical episodes attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively. We note that the RUG–IV Case-Mix Adjusted Federal Rate may vary for the same RUG, depending on whether the SNF was categorized as urban or rural.

Expressed as a ratio, the SNF services update factor would equal the following:

• The numerator is based on values applicable for the upcoming

performance period (PP) for which a target price is being calculated.

- The denominator is based on a blend of values applicable in the latest of the 3 historical years used in the target price (TP) calculations, weighted to account for values applicable prior to October 1, and values applicable starting October 1 when SNF PPS updates for the new fiscal year are in effect. Note that this weighting incorporates a modification to our proposed methodology for calculating update factors, as previously discussed in section III.C.4.(b)(4) of this final rule.

Therefore, the SNF services update factor formula is shown as—

$$\frac{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{PP}}{\text{Average RUG IV Case Mix Adjusted Federal Rate}_{TP}}$$

(e) HHA Services Update Factor

The proposed HHA services update factor would apply to payments for services included in the episode and paid under the HH PPS, but exclude payments for Low Utilization Payment Adjustment (LUPA) claims (claims with four or fewer home health visits) because they are paid differently and would instead be captured in the update factor for other services in section III.C.4.b.(f) of the proposed rule. The update factor applied to the home health services component of each participant hospital and region's historical average episode payments would be based on how inputs for the Medicare HH PPS have changed between the latest year used in the historical 3 years of episodes and the upcoming performance period under CJR. We proposed to use changes in the HH PPS base rate and average of home health resource group (HHRG) case-mix weight, inputs for the HHA PPS and defined in the HHA PPS Final Rule for the relevant years, to calculate the home health services update factor. The average HHRG case-mix weights would be specific to each participant hospital and region to account for hospital and region-specific home health service utilization patterns. Hospital-specific and region-specific HHA services update factors would be calculated by averaging the HHRG case-mix weights for all home health payments (excluding LUPA claims) included in the historical episodes attributed to each participant hospital and attributed to CJR eligible hospitals in the region, respectively.

Expressed as a ratio, the HHA adjustment factor would equal the following:

- The numerator is based on values applicable for the upcoming performance period (PP) for which a target price is being calculated.
- The denominator is based on values applicable at the end of the latest of the 3 historical years used in the target price (TP) calculations.

Therefore, the proposed HHA services update factor formula is shown as—

$$\frac{\text{60 Day Episode Rate}_{PP} * \text{average HHRG weight}_{PP}}{\text{60 Day Episode Rate}_{TP} * \text{average HHRG weight}_{TP}}$$

(f) Other Services Update Factor

The other services update factor would apply to payments for services included in the episode and not paid under the IPPS, MPFS, IRF PPS, or HHA PPS (except for LUPA claims). This component would include episode payments for home health LUPA claims and CJR related readmissions at CAHs. For purposes of calculating the other services update factor, we proposed to use the Medicare Economic Index (MEI), a measure developed by CMS for measuring the inflation for goods and services used in the provision of physician services.[28] We would calculate the other services update factor as the percent change in the MEI between the latest year used in the TP calculation and its projected value for the upcoming performance period. Because MEI is not hospital or region-specific, each participant hospital and region would use the same other services update factor.

[28] Medicare Market Basket Data. *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketData.html.*

(5) Blend Hospital-Specific and Regional Historical Data

We proposed to calculate CJR episode target prices using a blend of hospital-specific and regional historical average CJR episode payments, including CJR episode payments for all CJR eligible hospitals in the same U.S. Census division as discussed further in section III.C.4.b.(6) of the proposed rule. Specifically, we proposed to blend two-thirds of the hospital-specific episode payments and one-third of the regional episode payment to set a participant hospital's target price for the first 2-performance years of the CJR model (CY 2016 and CY 2017). For performance year 3 of the model (CY 2018), we proposed to adjust the proportion of the hospital-specific and regional episode payments used to calculate the episode target price from two-thirds hospital-specific and one-third regional to one-third hospital-specific and two-thirds regional. Finally, we proposed to use only regional historical CJR episode payments for performance years 4 and 5 of the model (CY 2019 and CY 2020) to set a participant hospital's target price, rather than a blend between the hospital-specific and regional episode payments. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of the proposed rule. We welcome comment on the appropriate blend between hospital-specific and regional episode payments and the change in that blend over time.

We considered establishing episode target prices using only historical CJR hospital-specific episode payments for all 5 performance years of the model (that is, episode payments for episodes attributed to the participant hospital, as previously described in section III.C.2. of the proposed rule). Using hospital-specific historical episodes may be appropriate in other models such as BPCI Model 2 where participation is voluntary and setting a region-wide target price could lead to a pattern of selective participation in which inefficient providers decline to participate, undermining the model's ability to improve the efficiency and quality of care delivered by those providers, while already-efficient providers receive windfall gains even if they do not further improve efficiency. Because CJR model participants will be required to participate in the model,

solely using hospital-specific historical episode data is not necessary to avoid this potential concern. Furthermore, using only hospital-specific historical CJR episode payments may provide little incentive for hospitals that already cost-efficiently deliver high quality care to maintain or further improve such care. These hospitals could receive a relatively low target price because of their historical performance but have fewer opportunities for achieving additional efficiency under CJR. They would not receive reconciliation payments for maintaining high quality and efficiency, while other hospitals that were less efficient would receive reconciliation payments for improving, even if the less historically efficient hospitals did not reach the same level of high quality and efficiency as the more historically efficient hospitals. Using only hospital-specific historical CJR episode payments may also not be sufficient to curb inefficient care or overprovision of services for hospitals with historically high CJR episode payments. In such instances, using hospital-specific historical episode payments for the CJR model could result in Medicare continuing to pay an excessive amount for episodes of care provided by inefficient hospitals, and inefficient hospitals would stand to benefit from making only small improvements. Thus, we did not propose to set target prices based solely on hospital-specific data for any performance years of the model.

We considered establishing the episode target price using only historical CJR regional episode payments for all 5 performance years of the model. Though regional target pricing would reward the most efficient hospitals for continuing to provide high quality and cost efficient care, we are concerned about providing achievable incentives under the model for hospitals with high historical CJR average episode payments. We stated in the proposed rule our belief that a lower regional price for such hospitals would leave them with little financial incentive in performance year 1, especially without any responsibility to repay payments in excess of the target price as described in section III.C.3. of the proposed rule. Thus, we did not propose to set target prices solely on regional data for the entire duration of the model.

Therefore, we proposed initially to blend historical hospital-specific and regional-historical episode payments and then transition to using regional-only historical episode payments in establishing target prices to afford early and continuing incentives for both historically efficient and less efficient hospitals to furnish high quality, efficient care in all years of the model. Our proposal more heavily weights a hospital's historical episode data in the first 2 years of the model (two-thirds hospital-specific, one-third regional), providing a reasonable incentive for both currently efficient and less efficient hospitals to deliver high quality and efficient care in the early stages of model implementation. Beginning in performance year 3, once hospitals have engaged in care redesign and adapted to the model parameters, we proposed to shift to a more heavily weighted regional contribution (one-third hospital-specific, two-thirds regional in performance year 3) and ultimately to a regional target price for performance years 4 and 5. We stated in the proposed rule our belief that by performance year 4, setting target prices based solely on regional historical data would be feasible because hospitals would have had 3 years under this model to more efficiently deliver high quality care, thereby reducing some of the variation across hospitals. We stated in the proposed rule our belief that transitioning to regional only pricing in the latter years of the model would provide important information about the reduction in unnecessary variation in LEJR episode utilization patterns within a region that can be achieved.

We stated in the proposed rule our belief that transitioning to regional-only pricing in the latter years of the model may provide valuable information regarding potential pricing strategies for successful episode payment models that we may consider for expansion in the future. As discussed previously, substantial regional and hospital-specific variation in Medicare LEJR episode spending currently exists for beneficiaries with similar demographic and health status, so we are proposing that the early CJR model years will more heavily weight historical hospital-specific experience in pricing episode for a participant hospital. Once the hospital has substantial experience with care redesign, we expect that unnecessary hospital-specific variation in episode spending will be minimized so that regional-only pricing would be appropriate as we have proposed. We noted that, like episode payment under the CJR model, Medicare's current payment systems make payments for bundles of items and services, although of various breadths and sizes depending on the specific payment system. For example, the IPPS pays a single payment, based on national prices with geography-specific labor cost adjustments, for all hospital services furnished during an inpatient hospitalization, such as nursing services, medications, medical equipment, operating room suites, etc. Under the IPPS, the national pricing approach incentivizes efficiencies and has, therefore, led to a substantial reduction in unnecessary hospital-specific variation in resource utilization for an inpatient hospitalization. On the other hand, the episode payment approach being tested under BPCI Model 2 relies solely on provider-specific pricing over the lifetime of the model, assuming the number of episode cases is sufficient to establish a reliable episode price, an approach that has potential limitations were expansion to be considered. Thus, we stated in the proposed rule our belief that our proposal for CJR will provide new, important information regarding pricing for even larger and broader bundles of services once unnecessary provider-specific variation has been minimized that would supplement our experience with patterns and pricing under existing payment systems and other episode payment models. We expect that testing of CJR will contribute further information about efficient Medicare pricing strategies that result in appropriate payment for providers' resources required to furnish high quality, efficient care to beneficiaries who receive LEJR procedures. This is essential information for any consideration of episode payment model expansion, including nationally, in the future, where operationally feasible and appropriate pricing strategies, including provider-specific, regional, and national pricing approaches would need to be considered.

We proposed an exception to the blended hospital-specific and regional pricing approach for hospitals with low historical CJR episode volume. We proposed to define hospitals with low CJR episode volume as those with fewer than 20 CJR episodes in total across the 3-historical-years used to calculate target prices. We stated in the proposed rule our belief that calculating the hospital-specific component of the blended target price for these historically low CJR episode volume hospitals may be subject to a high degree of statistical variation. Therefore, for each performance year, we proposed to use 100 percent regional target pricing for participant hospitals who have fewer than twenty historical CJR episodes in the 3-historical-years used to calculate target prices, as described in section III.C.4.b.(2) of the proposed rule. We note that the 3-historical-years used

to calculate target prices would change over the course of the model, as described in section III.C.4.b.(2) of the proposed rule, and when that happens, the twenty episode threshold would be applied to the new set of historical years. If all IPPS hospitals nationally participated (for estimation purposes, only) in CJR, we estimate about 5 percent of hospitals would be affected by this proposed low historical CJR episode volume provision.[29] A minimum threshold of twenty episodes is almost equal to the minimum number of admissions required in the Medicare HRRP. HRRP payment adjustment factors are, in part, determined by procedure/condition-specific readmission rates for a hospital. HRRP requires at least 25 procedure/condition-specific admissions to calculate the procedure/condition-specific readmission rate and to be included in the hospital's overall HRRP payment adjustment factor. Though the proposed minimum threshold of twenty episodes is slightly less than the 25 admissions required for HRRP, we stated in the proposed rule our belief that because we would not be calculating infrequent events such as readmissions, we can achieve a stable price with slightly fewer episodes.

We also proposed an exception to the blended hospital-specific and regional pricing approach for participant hospitals that received new CCNs during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. These participant hospitals with new CCNs may have formed due to a merger between or split from previously existing hospitals, or may be new hospitals altogether. As a general principle, we aim to incorporate into the target prices all the historical episodes that would represent our best estimate of CJR historical payments for these participant hospitals with new CCNs. For participant hospitals with new CCNs that formed from a merger between or split from previously existing hospitals, we proposed to calculate hospital-specific historical payments using the episodes attributed to the previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section. For participant hospitals with new CCNs that are new hospitals altogether, we proposed to use the approach previously described in this section for hospitals with fewer than 20 CJR episodes across the 3-historical-years used to calculate target prices. In other cases, due to an organizational change a hospital may experience a change to an already existing CCN during the 24 months prior to the beginning of, or during, the performance year for which target prices are being calculated. For example, one hospital with a CCN may merge with a second hospital assigned a different CCN, and both hospitals would then be identified under the single CCN of the second hospital. While there may be more than 20 CJR episodes under the second hospital's CCN in total across the 3-historical-years used to calculate target prices, in this scenario our use of only those cases under the second hospital's CCN in calculating hospital-specific historical payments would fail to meet our general principle of incorporating into target prices all the historical episodes that would represent our best estimate of CJR historical payments for these now merged hospitals. In this scenario, we proposed to calculate hospital-specific payments for the remaining single CCN (originally assigned to the second hospital only) using the historical episodes attributed to both previously existing hospitals. These hospital-specific historical payments would then be blended with the regional historical payments according to the approach previously described in this section in order to determine the episode price for the merged hospitals bearing a single CCN.

We sought comment on this proposed approach for blending hospital-specific and regional historical payments.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters supported the proposal to blend hospital-specific and regional historical episode data to calculate target prices. They explained that this balanced the incentivizes for already efficient hospitals to continue great performance, and allowed hospitals with historically high episode expenditures sufficient time to create care pathways and implement practice pattern changes before getting to 100 percent regional pricing in years 4 and 5 of the CJR model. Some other commenters recommended for hospital-specific pricing only because any definition of region would not properly account for variations due to factors such as patient characteristics, socioeconomic factors, and access to care.

Some commenters recommended that instead of blending regional and hospital-specific historical average CJR episode payments, we use the higher of the two to reward hospitals that are already efficient.

Some commenters recommended that we delay the transition to regional pricing in order to afford more time for hospitals with high historic episode expenditures, some commenters supported our proposal to get to 100 percent regional pricing by year 4, and some others recommended that we accelerate the transition to regional pricing to appropriately reward already efficient participant hospitals.

*Response:* We appreciate commenters' support for blending hospital-specific and regional historical episode data to calculate target prices. We appreciate that the pace of transitioning to regional pricing may benefit some participant hospitals more than others. However, we believe that the proposed approach to get to 100 percent regional pricing by year 4 strikes an appropriate balance between providing participant hospitals time to adapt while providing important information about the reduction in unnecessary variation in LEJR episode utilization patterns within a region that can be achieved.

We believe that only using hospital-specific pricing would not reward already efficient participant hospitals for maintaining high performance; participant hospitals that are already delivering efficient and high quality care would find it challenging to improve upon their own historical performance in order to qualify for reconciliation payments. Similarly, we believe that using the higher of regional and hospital-specific prices would not sufficiently incentivize inefficient participant hospitals to become more efficient; participant hospitals that have historically high episode expenditures would have less of an incentive to become significantly more efficient over the course of the model if they can qualify for reconciliation payments by improving only slightly relative to their own historical performance, while still being less efficient than their regional peers.

We acknowledge the importance of properly accounting for variations in patient-specific clinical characteristics, socioeconomic conditions, and access to care to appropriately incentivize participant hospitals to deliver high quality and efficient care. We refer readers to response to comments in section III.C.4.b.(1) of this final rule for further discussion on risk stratification to account for such variations. We also acknowledge that incorporating a regional component of historical episode data into a participant hospital's target prices may increase the presence of the variations as

[29] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

commenters stated, thereby making appropriate risk adjustment and/or risk stratification that much more important. As discussed in the response to comments in section III.C.4.b.(1) of this final rule, we will risk stratify based on anchor MS–DRG and hip fracture status, and we may explore more comprehensive risk adjustment approaches.

*Comment:* Several commenters recommended modifying the definition of low volume as it is used to determine which participant hospitals receive 100 percent regional target prices because they do not have a sufficient number of CJR episodes in the 3-historical-years of data used to calculate target prices. Commenters suggested increasing the low volume threshold for hospital-specific and regional target pricing from 20 to, for example, 100 episodes, because 20 episodes was not sufficient to remove random variation.

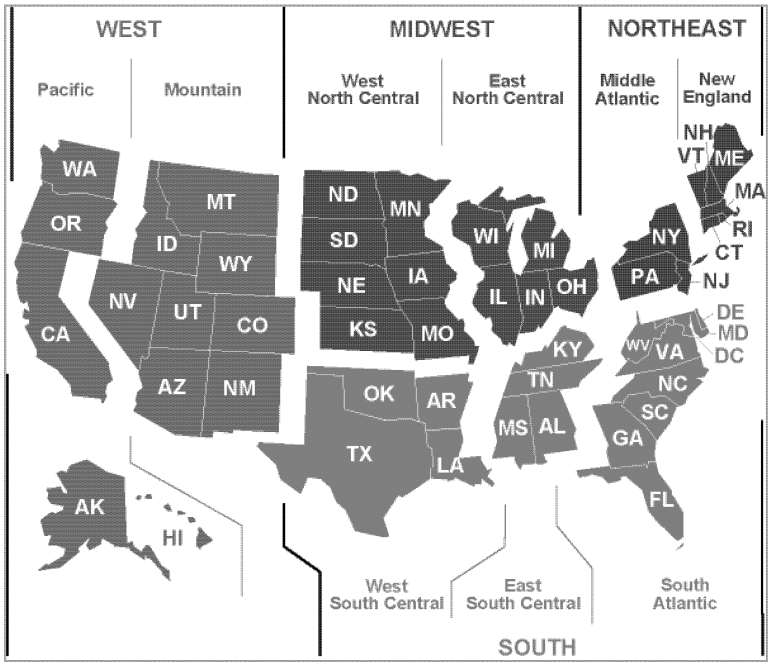
*Response:* We agree with commenters that a greater number of participant hospital-specific episodes would better remove the effects of random variation. However, if we increase the low volume threshold for blending hospital-specific and regional target prices, more participant hospitals would receive 100 percent regional prices in the first three performance years of the model, and their target prices would not incorporate any data from hospital-specific historical experience. Let us take as an example a participant hospital that has 50 episodes in the 3-historical-years of data used to calculate target prices for performance year 1, and let us assume that the hospital-specific portion of its target price is higher than the regional component. This participant hospital would need to become more efficient so as to achieve actual episode expenditures below its target prices. By blending the hospital-specific and regional components of the target price, this hospital has a higher target price than it would have had it received a 100 percent regional price. With the higher target price, the participant hospital has a greater opportunity to improve its efficiency and qualify for reconciliation payments. The blending of regional and hospital-specific target prices affords historically less efficient hospitals an opportunity to be rewarded for improvement in the earlier performance years, while they prepare for transitioning to 100 percent regional pricing by performance year 4. We want to afford this transition opportunity to as many participant hospitals as possible, while minimizing the effect of random variations for hospitals with few historical episodes. In the proposed rule, we compared our proposed low volume threshold of 20 episodes to the threshold used for Medicare's HRRP program. We continue to believe that 20 episodes in the 3-historical-years of data used to calculate target prices is the appropriate ''low volume'' threshold for blending target prices that mitigates effects of random variation while still incorporating hospital-specific historical experience and affording participant hospitals an opportunity to transition to 100 percent regional pricing.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to blend hospital-specific and regional historical expenditures in setting target prices, though we note that the term ''CJR eligible hospitals' is being renamed to ''CJR regional hospitals'' as discussed in response to comments in section III.C.4.b.(4) of this final rule.

(6) Define Regions as U.S. Census Divisions

In all 5 performance years we proposed to define ''region'' as one of the nine U.S. Census divisions [30] in Figure 3.

**FIGURE 3: U.S. CENSUS DIVISIONS**[31]




[30] There are four census regions—Northeast, Midwest, South, and West. Each of the four census regions is divided into two or more ''census divisions''.''. Source: *https://www.census.gov/geo/reference/gtc/gtc_census_divreg.html.*. Accessed on April 15, 2015.

We considered using states, HRRs, and the entire U.S. as alternative options to U.S. Census divisions in defining the region used in blending provider-specific and regional historical episode data for calculating target prices. However, HRR definitions are specifically based on referrals for cardiovascular surgical procedures and neurosurgery, and may not reflect referral patterns for orthopedic procedures. Using the entire U.S. would not account for substantial current regional variation in utilization, which is significant for episodes that often involve PAC use, such as LEJR procedures.[32] Finally, we considered using states as regions but were concerned that doing so would not allow for sufficient LEJR episode volume to set stable regional components of target prices, especially for participant hospitals in small states. We believe U.S. Census divisions provide the most appropriate balance between very large areas with highly disparate utilization patterns and very small areas that would be subject to price distortions due to low volume or hospital-specific utilization patterns.

We sought comment on our proposal to define a region as the U.S. Census division for purposes of the regional component of blended target prices under CJR.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters supported the use of U.S. Census divisions as regions. Some commenters, though, stated U.S. Census divisions are too large with significant practice and PAC access variations, resulting in different average historical expenditures across hospitals in the same U.S. Census division. Some commenters suggested an alternative of using MSAs as regions; MSAs would align with the provider selection process, and the smaller unit for regions would better capture regional practice pattern differences. Other commenters, including MedPAC, stated that we should define the entire nation as the region (that is, national pricing) because we should be striving towards eliminating regional variations in practice patterns.

*Response:* We appreciate commenters' support for the use of U.S. Census divisions as regions. Especially given that commenters proposed both larger regions (that is, national pricing) and smaller regions (that is, MSAs), we still believe U.S. Census divisions provide the most appropriate balance between very large areas with highly disparate utilization patterns and very small areas that would be subject to price distortions due to low volume or hospital specific utilization patterns.

*Comment:* Several commenters noted that some of the selected MSAs for participation in CJR span two different U.S. Census divisions. These commenters stated that the true cost for hospitals in the same MSA would likely not be different, and significant differences in pricing would create unfair market advantages due to a hospital's address within an MSA. They suggested blending the regional target price component of the two U.S. Census divisions that are being spanned for each of these MSAs, reflecting the distribution of the population within the MSA/census regions.

*Response:* We agree with commenters that the true cost for hospitals in the same MSA may not be different, and significant differences in pricing may create unfair market advantages due to a hospital's address within an MSA. We will modify our proposal and apply the same regional target price component to target pricing for all participant hospitals within an MSA, even if the MSA spans two U.S. Census divisions. There are three selected MSAs for participation in CJR that span two U.S. Census divisions: St. Louis, Cincinnati, and Cape Girardeau.

We considered the approach suggested by commenters—blending the two regional target price components based on the population distribution. However, using 2010 U.S. Census data, we determined that at least 75 percent of the population in the previously mentioned MSAs resides in just one of the U.S. Census divisions that the MSA spans. For simplicity, we will completely group MSAs that span U.S. Census divisions together with the U.S. Census divisions in which the Census estimates the majority of people reside, as shown in Table 9:

TABLE 9—REGION GROUPING FOR SELECTED MSAS THAT SPAN U.S. CENSUS DIVISIONS

| MSA | Original U.S. Census divisions spanned by MSA (state included in MSA) | U.S. Census division used for CJR region |
|---|---|---|
| St. Louis, MO-IL | West North Central (MO), East North Central (IL) | West North Central. |
| Cincinnati, OH-KY-IN | East North Central (OH, IN), East South Central (KY) | East North Central. |
| Cape Girardeau, MO-IL | West North Central (MO), East North Central (IL) | West North Central. |

*Final Decision:* After consideration of the public comments we received, we are modifying our proposal to define regions as U.S. Census divisions so as to ascribe the same regional component of target prices for participant hospitals in MSAs that span U.S. Census divisions. Specifically, as described in Table 9, selected MSAs that span U.S. Census divisions will be attributed to one U.S. Census division for purposes of calculating the regional component of CJR target prices.

(7) Normalize for Provider-Specific Wage Adjustment Variations

We note that some variation in historical CJR episode payments across hospitals in a region may be due to wage adjustment differences in Medicare's payments. In setting Medicare payment rates, Medicare typically adjusts facilities' costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative wage level in the geographic area of the facility or practitioner (or the beneficiary residence, in the case of home health and hospice services) compared to a national average wage level. Such adjustments are essential for setting accurate payments, as wage levels vary significantly across geographic areas of the country. However, having the wage level for one hospital influence the regional-component of hospital-specific and regional blended target prices for another hospital with a different wage level would introduce unintended pricing distortions not based on utilization pattern differences.

[31] *http://www.eia.gov/consumption/commercial/census_maps.cfm.*

[32] Hussey PS, Huckfeldt P, Hirshman S, Mehrotra A. Hospital and regional variation in Medicare payment for inpatient episodes of care [published online April 13, 2015]. JAMA Intern Med. doi:10.1001/jamainternmed.2015.0674.

In order to preserve how wage levels affect provider payment amounts, while minimizing the distortions introduced when calculating the regional-component of blended target prices, we proposed to normalize for wage index differences in historical episode payments when calculating and blending the regional and hospital-specific components of blended target prices. Calculating blended target prices from historical CJR episodes would help ensure we incentivize hospitals based on historical utilization and practice patterns, not Medicare payment system rate changes that are beyond hospitals' control.

We proposed to normalize for provider-specific wage index variations using the IPPS wage index applicable to the anchor hospitalization (that is, the IPPS wage index used in the calculation of the IPPS payment for the anchor hospitalization). The anchor hospitalization accounts for approximately 50 percent of the total episode expenditures, and the IPPS wage index is applied to IPPS payments in a similar manner as wage indices for other Medicare payment systems are applied to their respective payments.[33] Therefore, we proposed that the IPPS wage index applicable to the anchor hospitalization for each historical episode be used to normalize for wage index variations in historical episode payments across hospitals when calculating blended target prices. We proposed to specifically perform this normalization using the wage normalization factor (0.7 * IPPS wage index + 0.3) to adjust the labor-related portion of payments affected by wage indices. The 0.7 approximates the labor share in IPPS, IRF PPS, SNF, and HHA Medicare payments. We would normalize for provider-specific wage index variations by dividing a hospital's historical episode payments by the wage normalization factor.

We proposed to reintroduce the hospital-specific wage variations by multiplying episode payments by the wage normalization factor when calculating the target prices for each participant hospital, as described in section III.C.4.c. of the proposed rule. When reintroducing the hospital-specific wage variations, the IPPS wage index would be the one that applies to the hospital during the period for which target prices are being calculated (for example, FY 2016 wage indices for the target price calculations for episodes that begin between January 1 and September 30, 2016). The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of the proposed rule. We sought comment on our proposal to normalize for wage index differences using participant hospitals' wage indices in order to calculate blended target prices.

The following is a summary of the comments received and our responses.

*Comment:* Commenters emphasized the need to account for wage index differences. Not accounting for these differences accurately may unfairly disadvantage some hospitals. Some commenters expressed concern about using 0.7 as the labor share for the labor related portions of Medicare FFS payments; the weight index weight varies by Medicare FFS payment system, and in IPPS in particular, the weight can be either 0.688 or 0.620, depending on the IPPS hospital's wage index. Some other commenters noted that using only the IPPS wage index for the anchor hospital would not accurately normalize expenditures for PAC providers who have their own wage indices. Some of these commenters recommended we blend hospital and PAC providers' wage indices. Some commenters requested clarification on how we would account for wage index differences between baseline and performance periods.

*Response:* We acknowledge the need to accurately account for wage index differences so that we incentivize based on practice patterns and not Medicare FFS fee schedule differences. We recognize that the proposed approach of using the anchor hospital's wage index and 0.7 as the labor share for the labor related portions of Medicare FFS payments would only approximately normalize and reapply wage indices.

In response to commenters, we will modify our proposal and normalize for wage indices at the claim level for both historical episode expenditures and actual episode expenditures in each performance year by using the wage index normalization algorithm included in the CMS Price (Payment) Standardization Detailed Methodology discussed in section III.C.3 of this final rule, the same methodology we finalized to exclude the various special payment provisions in calculating episode expenditures. By normalizing claims for wage indices in the historical episode expenditure data at the claim level, we will accurately account for wage indices and labor shares for various providers and suppliers under the different Medicare FFS payment systems. This will be a more accurate way than what we proposed to achieve the same goal of accounting for wage index differences so that we incentivize based on practice patterns and not Medicare FFS wage adjustment differences. We will also normalize claims for wage indices in performance year data, as we discuss further in response to comments in section III.C.6.a. of this final rule.

We believe it is still important to reintroduce wage index variations near the end of the target price calculation methodology. Participant hospitals may use their reconciliation payments to invest in care coordination or care delivery infrastructure, and we expect that the costs for such investments would vary by geography due to differences in local wages. For example, we expect that hiring a care coordinator would cost a participant hospital more in the New York metro region than in a rural part of New Mexico. If we do not reintroduce wage index variations into target price calculations, we would calculate reconciliation and repayment amounts that would not capture labor cost variation throughout the country, and participant hospitals in higher labor cost regions may see relatively less financial incentive to invest in improved care quality and efficiency. We intend to incentivize all hospitals to reduce episode spending under the CJR model, regardless of local labor cost variations.

We will use the proposed approach to reintroduce wage index variations—apply the participant hospital's wage index to episode spending, using 0.7 as the labor share. While commenters are correct that the IPPS labor share can be 0.688 or 0.620, depending on the participant hospital's wage index, the labor share for PAC providers also varies across Medicare FFS payment systems: ~0.695 for SNF PPS and IRF PPS, and ~0.785 for HH PPS. Given this range for the labor share across Medicare FFS payment systems, we believe that using 0.7 is an appropriate estimate of the labor share for reintroducing wage index variations. Additionally, as commenters pointed out, PAC providers have their own wage indices. Because wage index variations are reintroduced near the end of the target price calculation methodology and after other features, such as blending, pooling, and update factors are applied, we do not believe there is a simple approach to reintroduce wage index variations at the claim level. We acknowledge that using the participant hospital's wage index and 0.7 as the labor share would only be an approximation of the wage index variations, but this approximation would not change whether a participant hospital qualifies for reconciliation

[33] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

payments or is obligated to repay Medicare because we would apply wage index normalization at the claim level for both target price calculations (as previously discussed) as well as calculations of actual episode spending (as discussed in response to comments in section III.C.6.a. of this final rule), and the wage index variation would be reintroduced in the same manner to both target price calculations (as previously discussed) and actual episode spending calculations (as discussed in response to comments in section III.C.6.a. of this final rule). We believe that this approach to reintroducing wage index variations is sufficient to modulate the reconciliation and repayment amounts to reflect local labor cost variations.

*Final Decision:* After consideration of the public comments we received, we are modifying our proposal so as to normalize for wage indices at the claim level by using the wage index normalization algorithm included in the CMS Price (Payment) Standardization Detailed Methodology discussed in section III.C.3., the same claim-level standardization methodology we finalized in section III.C.3.a. to exclude the various special payment provisions in calculating episode expenditures. We are finalizing the proposal to reintroduce wage index differences into calculations of historical and actual episode spending based on the participant hospital's wage index and 0.7 as the labor cost share.

(8) Combination of CJR Episodes Anchored by MS–DRGs 469 and 470

We proposed to pool together CJR episodes anchored by MS–DRGs 469 and 470 for target price calculations to use a greater historical CJR episode volume and set more stable target prices. We note that we would still calculate separate target prices for episodes anchored by MS–DRGs 469 versus 470, described later in this section.

To pool together MS–DRG 469 and 470 anchored episodes, we proposed to use an anchor factor and hospital weights. The anchor factor would equal the ratio of national average historical MS–DRG 469 anchored episode payments to national average historical MS–DRG 470 anchored episode payments. The national average would be based on episodes attributed to any CJR eligible hospital. The resulting anchor factor would be the same for all participant hospitals. For each participant hospital, a hospital weight would be calculated using the following formula, where episode counts are participant hospital-specific and based on the episodes in the 3-historical-years used in target price calculations:

$$\frac{\textit{Count of MS DRG 469 and MS DRG 470 anchored episodes}}{\textit{MS DRG 469 anchored episode count} * \textit{anchor factor} + \textit{MS DRG 470 anchored episode count}}$$

A hospital-specific pooled historical average episode payment would be calculated by multiplying the hospital's hospital weight by its combined historical average episode payment (sum of MS–DRG 469 and 470 anchored historical episode payments divided by the number of MS–DRG 469 and 470 historical episodes).

The calculation of the hospital weights and the hospital-specific pooled historical average episode payments would be comparable to how case mix indices are used to generate case mix-adjusted Medicare payments. The hospital weight essentially would count each MS–DRG 469 triggered episode as more than one episode (assuming MS–DRG 469 anchored episodes have higher average payments than MS–DRG 470 anchored episodes) so that the pooled historical average episode payment, and subsequently the target price, is not skewed by the hospital's relative breakdown of MS–DRG 469 versus 470 anchored historical episodes.

The hospital-specific pooled historical average payments would be modified by blending and discount factors, as described in section III.C.4.c. of the proposed rule. Afterwards, the hospital-specific pooled calculations would be ''unpooled'' by setting the MS–DRG 470 anchored episode target price to the resulting calculations, and by multiplying the resulting calculations by the anchor factor to produce the MS–DRG 469 anchored target prices.

We would calculate region-specific weights and region-specific pooled historical average payments following the same steps proposed for hospital-specific weights and hospital-specific pooled average payments. Instead of grouping episodes by the attributed hospital as is proposed for hospital-specific calculations, region-specific calculations would group together episodes that were attributed to any CJR eligible hospital located within the region. The hospital-specific and region-specific pooled historical average payments would be blended together as discussed in section III.C.4.b.(3) of the proposed rule. The specific order of steps, and how this step fits in with others, is discussed further in section III.C.4.c. of the proposed rule.

We considered an alternative option of independently setting target prices for MS–DRG 470 and 469 anchored episodes without pooling them. However, hospital volume for MS–DRG 469 was substantially less than for MS–DRG 470. In 2013 across all IPPS hospitals, there were more than 10 times as many MS–DRG 470 anchored episodes as compared to MS–DRG 469 anchored episodes.[34] In the same analysis, the median number of episodes for a hospital with at least 1 episode for the MS–DRG anchored episode was more than 80 for MS–DRG 470 anchored episodes, though fewer than 10 for MS–DRG 469 anchored episodes. Calculating target prices for MS–DRG 469 anchored episodes separately for each participant hospital may result in too few historical episodes to calculate reliable target prices. We also considered pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights. However, internal analyses suggest that average episode payments for these two MS–DRG anchored episodes significantly differed; CJR episodes initiated by MS–DRG 469 had payments almost twice as large as those initiated by MS–DRG 470.[35] This difference is reasonable given that Medicare IPPS payments differ for MS–DRG 469 and 470 admissions, and inpatient payments comprise approximately 50 percent of CJR episode payments. Thus, pooling together MS–DRG 469 and 470 anchored episodes without any anchor factor or hospital weights would introduce distortions due only to case-mix differences.

The following is a summary of the comments received and our responses.

[34] Source: CCW Part A and Part B claims for CJR episodes beginning in CY 2013.

[35] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

*Comment:* Many commenters requested for risk adjustment based on patients' hip fracture status, among other clinical and demographic dimensions.

*Response:* We refer readers to comments and responses to comments in section III.C.4.b.(1) of this final rule for further discussion on risk stratification, and we reference it here because changes to risk stratification would impact how we would combine CJR episodes anchored by MS–DRGs 469 and 470. As discussed in the responses to comments in section III.C.4.b.(1) of this final rule, we will modify our proposal so as to risk stratify and set different target prices both for episodes anchored by MS–DRG 469 vs. MS–DRG 470 and for episodes with hip fractures vs. without hip fractures. To fully incorporate this change, we will also modify the proposed approach to calculate anchor factors and hospital and regional weights so as to apply them to four groups of target prices, instead of two groups; otherwise, the approach will be the same as proposed. Specifically, we will have three anchor factors, instead of one:

$$anchor\ factor\ for\ MS-DRG\ 469\ with\ hip\ fracture = \frac{Natl.avg.\ MS-DRG\ 469\ with\ hip\ fracture\ episode\ spend}{Natl.avg.MS-DRG\ 470\ without\ hip\ fracture\ episode\ spend}$$

$$anchor\ factor\ for\ MS-DRG\ 469\ without\ fracture = \frac{Natl.avg.\ MS-DRG\ 469\ without\ hip\ fracture\ episode\ spend}{Natl.avg.MS-DRG\ 470\ without\ hip\ fracture\ episode\ spend}$$

$$anchor\ factor\ for\ MS-DRG\ 470\ with\ hip\ fracture = \frac{Natl.avg.\ MS-DRG\ 470\ with\ hip\ fracture\ episode\ spend}{Natl.avg.MS-DRG\ 470\ without\ hip\ fracture\ episode\ spend}$$

Additionally, hospital and regional weights will be calculated using the following formula:

$$\frac{Count\ of\ MS\ DRG\ 469\ and\ MS\ DRG\ 470\ anchored\ episodes}{\begin{array}{c}MS\ DRG\ 469\ anchored\ with\ hip\ fracture\ episode\ count*anchor\ factor\ for\ MS-DRG\ 469\ with\ hip\ fracture\ +\\ MS-DRG\ 469\ anchored\ without\ hip\ fracture\ episode\ count*anchor\ factor\ for\ MS-DRG\ 469\ without\ fracture+\\ MS-DRG\ 470\ anchored\ with\ hip\ fracture\ episode\ count*anchor\ factor\ for\ MS-DRG\ 470\ with\ hip\ fracture+\\ MS\ DRG\ 470\ anchored\ without\ hip\ fracture\ anchored\ episode\ count\end{array}}$$

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, with modification to calculate anchor factors and hospital and regional weights while incorporating the previously discussed changes to risk adjust not only on anchor MS–DRG but also hip fracture status. Additionally, note that the term ''CJR eligible hospitals'' is being renamed to ''CJR regional hospitals'' as discussed in response to comments in section III.C.4.b.(4) of this final rule.

(9) Discount Factor

When setting an episode target price for a participant hospital, we proposed to apply a discount to a hospital's hospital-specific and regional blended historical payments for a performance period to establish the episode target price that would apply to the participant hospital's CJR episodes during that performance period and for which the hospital would be fully, or partly, accountable for episode spending in relationship to the target price, as discussed in section III.C.3. of the proposed rule. We expect participant hospitals to have significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because this model would facilitate the alignment of financial incentives among providers caring for beneficiaries throughout the episode. This discount would serve as Medicare's portion of reduced expenditures from the CJR episode, with any episode expenditure below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred. We proposed to apply a 2 percent discount for performance years 1 through 5 when setting the target price. We stated our belief in the proposed rule that applying a 2 percent discount in setting the episode target price allows Medicare to partake in some of the savings from the CJR model, while leaving considerable opportunity for participant hospitals to achieve further episode savings below the target price that they would be paid as reconciliation payments, assuming they meet the quality requirements as discussed in section III.C.5 of the proposed rule.

The proposed 2 percent discount is similar to the range of the discounts used for episodes in the ACE demonstration.[36] In the Medicare ACE,

[36] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/*

Continued

a demonstration program that included orthopedic procedures such as those included in CJR, participant hospitals negotiated with Medicare discounts of 2.5 to 4.4 percent of all Part A orthopedic services and 0.0 to 4.4 percent of all Part B orthopedic services during the inpatient stay (excluding PAC). Hospitals received the discounted payment and reported that they were still able to achieve savings.[37] We stated our belief in the proposed rule that there is similar, if not potentially more, opportunity for savings in the CJR payment model because it includes acute inpatient, as well as PAC, an area of episode spending that accounts for approximately 25 percent of CJR episode payments and exhibits more than 2 times the episode payment variation [38] than that of acute inpatient hospitalization.[39] We stated in the proposed rule our belief that with the proposed 2 percent discount, participant hospitals have an opportunity to create savings for themselves as well as Medicare, while also maintaining or improving quality of care for beneficiaries.

The proposed 2 percent discount also matches the discount used in the BPCI Model 2 90-day episodes, and is less than the discount used in BPCI Model 2 30-day and 60-day episodes (3 percent). Hundreds of current BPCI participants have elected to take on responsibility for repayment in BPCI Model 2 with a 2 to 3 percent discount. Because many BPCI participants volunteered to participate in a bundled payment model with a discount, we stated in the proposed rule our belief that a discount percent that is within, and especially a discount of 2 percent that is at the lower end of, the BPCI discount range would allow CJR participant hospitals to create savings for both themselves and Medicare.

As stated previously in section III.C.3. of the proposed rule, we proposed to phase in the financial responsibility of hospitals for repayment of actual episode spending that exceeds the target price starting in performance year 2. In order to help hospitals transition to taking on this responsibility, we proposed to apply a reduced discount of one percent in performance year 2 for purposes of determining the hospital's responsibility for excess episode spending, but maintain the 2 percent discount for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price. For example, under this proposal in performance year 2, a hospital that achieves CJR actual episode payments below a target price based on a 2 percent discount would retain savings below the target price, assuming the quality thresholds for reconciliation payment eligibility are met (discussed in section III.C.5. of the proposed rule) and the proposed performance year stop-gain limit (discussed in section III.C.8. of the proposed rule) does not apply. Medicare would hold responsible for repayment hospitals whose CJR actual episode payments exceed a target price based on a one percent discount, assuming the proposed performance year 2 stop-loss limit (discussed in section III.C.8. of the proposed rule) does not apply. Hospitals that achieve CJR actual episode payments between a 2 percent-discounted target price and 1 percent-discounted target price would neither receive reconciliation payments nor be held responsible for repaying Medicare. The decision on which percent-discounted target price applies will be made by evaluating actual episode payments in aggregate after the completion of performance year 2, and the same percent-discounted target price would apply to all episodes that are initiated in performance year 2. We proposed to apply this reduced one percent discount for purposes of hospital repayment responsibility only in performance year 2 and apply the 2 percent discount for excess episode spending repayment responsibility for performance years 3 through 5. Under this proposal, the discount for determination of reconciliation payment for episode actual spending below the target price would not deviate from 2 percent through performance years 1 through 5.

In section III.C.5. of the proposed rule, we proposed voluntary submission of data for a patient-reported outcome measure. We proposed to incent participant hospitals to submit data on this measure by reducing the discount percentage by 0.3 percentage points for successfully submitting data, as defined in section III.D. of the proposed rule. By successfully submitting data on this metric for episodes ending in performance years 1, 2, 3, 4, and or 5, we would adjust the discount percentage in the corresponding year(s) as follows:

- For episodes beginning in performance year 2, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price, and set the discount percentage in a range from 1 percent to 0.7 percent for purposes of determining the amount the hospital would be responsible for repaying Medicare for actual episode spending above the target price.
- For episodes beginning in performance years 3 through 5, set the discount percentage in a range from 2 percent to 1.7 percent for purposes of reconciliation payment and Medicare repayment calculations.

The determination of whether the hospital successfully submitted data on the patient-reported outcome measure cannot be made until after the performance year ends and data is reported. Therefore, participant hospitals would be provided target prices for both scenarios whether the successfully submit data or not and such determination will happen at the time of payment reconciliation (discussed further in section III.C.6. of the proposed rule).

We sought comment on our proposed discount percentage of 2 percent for CJR episodes, our proposal to reduce the discount to 1 percent on a limited basis in performance year 2, and our proposal to reduce the discount by 0.3 percentage points for successfully reporting patient-reported outcomes data in the corresponding year.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters expressed concern about participant hospitals taking on financial risk in the CJR model. We refer readers to comments in section III.C.2, of this final rule for more discussion of such comments, and we reference them here because these comments may impact how the proposed discount factor is used to phase in risk for participant hospitals.

*Response:* As discussed in the responses to comments in section III.C.2. of this final rule, we appreciate commenters' concerns about participant hospitals' ability to manage risk. In the proposed rule, we proposed to use several design elements to phase in risk to better help transition participant hospitals. One of these design elements to phase risk in was the use of a reduced discount factor by 1 percentage point for

*files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.* Accessed April 16, 2015.

[37] IMPAQ International. Evaluation of the Medicare Acute Care Episode (ACE) Demonstration: Final Evaluation Report. Columbia, MD: IMPAQ International; May 2013. *http://downloads.cms.gov/files/cmmi/ACE-EvaluationReport-Final-5-2-14.pdf.* Accessed April 16, 2015.

[38] Variation for purposes of this calculation refers to standard deviation of inpatient and institutional post-acute episode payments as a percentage of average inpatient and post-acute episode payments, respectively.

[39] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

purposes of calculating repayment amounts in performance year 2, as discussed earlier in this section. In response to commenters' concerns, we will extend the use of a reduced discount factor for purposes of calculating repayment amounts to apply not only in performance year 2, but also in performance year 3.

*Comment:* Many commenters offered a variety of suggestions to CMS's proposal and alternatives considered to link quality and payment in the CJR model, including varying the discount percentage incorporated in the target price at reconciliation based on the participant hospital's quality performance. We refer readers to comments in section III.C.5 of this final rule for greater discussion of comments on linking quality and payment in the CJR mode.

*Response:* As discussed in the responses to comments later in this final rule in section III.C.5. of this final rule, we are modifying the proposed rule so as to use a composite score methodology to link quality and payment in the CJR model. With this composite score methodology, each hospital will receive a discount factor of 3 percent, though the discount factor would be 2 percent for purposes of calculating repayments to Medicare in performance years 2 and 3, reflecting the proposed discount factor reduction by 1 percentage point and the extension to performance year 3 of this reduction, to phase in downside risk, as discussed in the previous response.

Each participant hospital may qualify for a quality incentive payment. The quality incentive payment would not be a separate payment stream, but rather it would alter a hospital's effective discount factor used to calculate its target prices. Depending on a participant hospital's quality performance, in performance years 1, 4, and 5, the quality incentive payments could result in effective discount factors ranging from 3 percent to 1.5 percent. In performance years 2 and 3, the quality incentive payments could result in effective discount factors for purposes of calculating reconciliation payments ranging from 3 percent to 1.5 percent, and for purposes of calculating repayment amounts from 2 percent to 0.5 percent. We note that the lower effective discount factors for calculating repayment amounts in performance years 2 and 3 reflect the reduction by 1 percentage point in discount factor to phase in downside risk.

If hospitals' quality performance during the CJR model mirrors historical quality performance, we expect the majority of the participant hospitals to qualify for an effective discount factor of 2 percent each performance year for purposes of reconciliation payment calculations, the same discount factor proposed for all participant hospitals in the proposed rule. By using a range of discount factors, we will offer more participant hospitals an opportunity to qualify for reconciliation payments, and we will be able to better reward the highest quality participant hospitals.

We refer readers to responses to comments in section III.C.5 of this final rule for more details on quality incentive payments, effective discount factors, the link between quality and payment, and how participant hospitals may perform based on historical quality performance.

*Comment:* Some commenters recommended that we not apply a discount factor to any hospital because it would effectively function as a rate cut for MS–DRGs 469 and 470. Some of these commenters suggested we could achieve savings using a shared savings methodology (for example, participant hospitals would receive 50 percent of actual episode performance below undiscounted target prices, and would repay 50 percent of actual episode performance above undiscounted target prices).

*Response:* We disagree with commenters that a discount factor is the equivalent of a rate cut. We are providing participant hospitals the opportunity to qualify for reconciliation payments for delivering high quality and efficient care for LEJR episodes, and reconciliation payments may likely exceed the value of the discount factor.

The discount factor will serve as Medicare's portion of reduced expenditures from the CJR episode. We acknowledge that there are other potential mechanisms, including shared savings methodologies, to provide savings to Medicare while also incentivizing participant hospitals. However, we also believe that a discount model, as proposed, can also incentivize participant hospitals to deliver high quality and efficient care while also providing savings to Medicare. We appreciate commenters' suggestions and we may consider alternative methodologies, such as shared savings, in the future.

*Comment:* Several commenters requested that we not apply a discount factor to hospitals that are already efficient because they would not be able to achieve further efficiencies. It would be challenging for these efficient hospitals to qualify for reconciliation payments if benchmarked against a target price that incorporates a discount factor.

*Response:* Commenters' concerns could be valid if we were basing target prices only on hospital-specific episode expenditure data. However, because we are blending hospital-specific and regional components in the target price calculation, and transitioning to completely regional target prices by performance year 4, target prices for more efficient hospitals likely would be higher than what they would be under a hospital-specific only pricing approach. We believe that with the blending and transition to regional pricing, historically efficient and high quality participant hospitals have a significant opportunity to qualify for reconciliation payments. Additionally, as discussed in the response to comments in section III.C.5. of this final rule, we are modifying our proposal to provide lower effective discount factors used to calculate target prices for participant hospitals with better quality performance. Therefore, high quality participant hospitals will have a lower hurdle to overcome to qualify for reconciliation payments. We will continue to incorporate a discount percentage into the target price for every participant hospital, and we will use a reduced discount factor for participant hospitals with high quality performance, as stated previously in this section's responses to comments and in section III.C.5. of this final rule.

*Comment:* Commenters requested upfront investments to fund care delivery (for example, care coordination), infrastructure, and quality reporting changes that participant hospitals may need to make, similar to how some ACOs use upfront investments in other models and programs (for example, an initiative similar to the ACO Investment Model for Medicare Shared Savings Program participants). Commenters suggested we fund these upfront investments in a number of ways, including the following: a supplemental lump sum payment at the start of the model; increase, instead of discount, historical episode expenditures by 2 percent; or transition in an increasing discount factor, getting to 2 percent by the end of the model.

*Response:* We thank the commenter for the suggestion and for recognizing the importance of potential care delivery, infrastructure, and quality reporting changes participant hospitals may need to make for an episode-based payment model such as CJR. However, we do not believe that an additional upfront payment mechanism such as a per-beneficiary-per-month payment or an additional payment per episode will be necessary for hospitals to

successfully participate in this model. In BPCI, a similar episode-based payment model, participants have been able to improve episode expenditure performance without such additional upfront payment mechanisms.

Additionally, we believe there may be low investment opportunities for participant hospitals to achieve high quality and efficiency and qualify for reconciliation payments in this model. For example, participant hospitals may refer to high quality and efficient PAC providers when appropriate, and updates to discharge and referral patterns may be informed using already publicly available quality data and historical episode expenditure data provided by CMS and discussed in section III.E. of this final rule. PAC expenditures account for a significant proportion of historical CJR episode expenditures (approximately 30 percent [40]), and changes to discharge and referral patterns could have significant impact on participant hospitals' actual episode expenditure performance. We note that this rationale may not hold true for other models (for example, patient-centered medical homes, ACOs) where providers are responsible for beneficiaries' cost of care over a longer period of time.

We also reiterate that as discussed in section III.C.5.b. of this final rule, the quality measures selected for this model are already in use for mandatory CMS quality reporting programs, such as the IQR program. Hospitals will not experience an additional reporting burden under this model for such measures. In addition, while we are including testing of a voluntary patient-reported outcomes measures, as discussed in section III.C.5.b.2. of this final rule, reporting of this measure will be voluntary. We do not believe there is any required additional burden on participant hospitals to report quality data.

Given the success of participants in a similar model, the possibility to achieve reconciliation payments with relatively low investment approaches, and the lack of required additional quality reporting burden, we will not make additional upfront payments through mechanisms such as per-beneficiary-per-month payments or additional payments per episode.

*Final Decision:* After consideration of the public comments we received, we are modifying our proposal to use a composite score methodology to link quality and payment in the CJR model. With this composite score methodology, a participant hospital may qualify for a reconciliation payment and for different effective discount factors depending on its quality performance. We refer readers to section III.C.5. of this final rule more details on how quality and payment will be linked.

[40] Medicare FFS Parts A and B claims, CJR episodes, as proposed in this rule, between October 2013 and September 2014.

c. Approach To Combine Pricing Features

In section III.C.4.(b) of the proposed rule we discuss the various features we proposed to incorporate into our approach to set target prices. We refer readers to that section for more information on rationale and alternatives considered for each feature. In this section we discuss how the different pricing features, as well as the episode definition (section III.B. of the proposed rule) and adjustments to payments included in the episodes (section III.C.3. of the proposed rule), would fit together and be sequenced to calculate CJR episode target prices for participant hospitals. The following steps would be used to calculate MS–DRG 469 and 470 anchored episode target prices for both January 1 through September 30 and October 1 through December 31 each performance year. The output of each step would be used as the input for the subsequent step, unless otherwise noted.

- (1) Calculate historical CJR episode payments for episodes that were initiated during the 3-historical-years (section III.C.4.b.(2) of the proposed rule) for all CJR eligible hospitals for all Medicare Part A and B services included in the episode. We note that specific Per Beneficiary Per Month (PBPM) payments may be excluded from historical episode payment calculations as discussed in section III.C.7.d. of the proposed rule.
- (2) Remove effects of special payment provisions (section III.C.3.a. of the proposed rule).
- (3) Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.C.3.b of the proposed rule.).
- (4) Normalize for hospital-specific wage adjustment variation by dividing the episodes outputted in step (3) by the hospital's corresponding wage normalization factor described in section III.C.4.b.(7) of the proposed rule.
- (5) Trend forward 2 oldest historical years of data to the most recent year of historical data. As discussed in section III.C.4.b.(3) of the proposed rule, separate national trend factors would be applied to episodes anchored by MS–DRG 469 versus MS–DRG 470.
- (6) Cap high episode payment episodes with a region and MS–DRG anchor-specific high payment ceiling as discussed in section III.C.3.c. of the proposed rule, using the episode output from the previous step. We have posted region-specific historical average episode payments on the CJR Web site at *http://innovation.cms.gov/initiatives/CJR/*. Note that these historical average episode payments were based on our proposed policies and do not represent actual target prices or the regional portion of actual target prices under the model.
- (7) Calculate anchor factor and participant hospital-specific weights (section III.C.4.b.(8) of the proposed rule) using the episode output from the previous step to pool together MS–DRG 469 and 470 anchored episodes, resulting in participant hospital-specific pooled historical average episode payments. Similarly, calculate region-specific weights to calculate region-specific pooled historical average episode payments.
- (8) Calculate participant hospital-specific and region-specific weighted update factors as described in section III.C.4.b.(4) of the proposed rule. Multiply each participant hospital-specific and region-specific pooled historical average episode payment by its corresponding participant hospital-specific and region-specific weighted update factors to calculate participant hospital-specific and region-specific updated, pooled, historical average episode payments.
- (9) Blend together each participant hospital-specific updated, pooled, historical average episode payment with the corresponding region-specific updated, pooled, historical average episode payment according to the proportions described in section III.C.4.b.(5) of the proposed rule. Participant hospitals that do not have the minimum episode volume across the historical 3 years would use 0.0 percent and 100 percent as the proportions for hospital and region, respectively.
- (10) Reintroduce hospital-specific wage variations by multiplying the participant hospital-specific blended, updated, and pooled historical average episode payments by the corresponding hospital-specific wage normalization factor, using the hospital's IPPS wage index that applies to the hospital during the period for which target prices are being calculated (section III.C.4.b.(7) of the proposed rule).
- (11) Multiply the appropriate discount factor, as discussed in section III.C.4.b.(9) of the proposed rule to each participant hospital's wage-adjusted, blended, updated, and pooled historical

average episode payment. For performance years 1, 3, 4, and 5, two discount factors would be used, one if the hospital successfully submits data on the patient-reported outcomes measure proposed in section III.C.5. of the proposed rule, and one if the hospital does not successfully submit the data. For performance year 2, 4 discount factors would be used to account for the 4 combinations of the following: (a) Whether or not the hospital successfully submits data on the patient-reported outcomes measure; and (b) for the different discount factors proposed for purposes of calculating reconciliation payments vs. calculating repayment amounts. The result of this calculation would be the participant hospital-specific target prices for MS–DRG 470 anchored episodes.

• (12) Multiply participant hospitals' target prices for MS–DRG 470 anchored episodes by the anchor factor (section III.C.4.b.(8) of the proposed rule) to calculate hospitals' target prices for MS–DRG 469 anchored episodes.

The previously stated twelve steps would be used to calculate target prices for episodes that begin between January 1 and September 30, as well as for episodes that begin between October 1 and December 31, for each performance year. The target price calculations for the two different time periods each performance year would differ by the IPPS wage index used in step (11) and the update factors used in step (8). By following these twelve steps, we would calculate target prices for each participant hospital for each performance year. We refer readers to section III.C.4.b. of the proposed rule for further details on each of the specific steps.

We sought comment on the proposed approach to sequence and fit together the different pricing features, the episode definition (section III.B. of the proposed rule), and adjustments to payments included in the episodes (section III.C.3. of the proposed rule) to calculate CJR episode target prices for participant hospitals.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters requested for risk adjustment based on patients' hip fracture status, among other clinical and demographic dimensions. Commenters also recommended that we modify the definition of ''CJR eligible hospitals'', the term used to identify hospitals included in calculations for the regional component of target prices, to not exclude hospitals that are participating in BPCI.

*Response:* We refer readers to comments and responses to comments in sections III.C.4.b.(1) and III.C.4.b.(4) of the final rule for further discussion on risk stratification and CJR eligible hospitals, respectively. We reference them here because changes to risk stratification and CJR eligible hospitals would impact how we would combine CJR pricing features. Given the changes to the proposed rule described in sections III.C.3, III.C.4.b, and III.C.5, we are modifying the different pricing features would fit together and be sequenced to calculate CJR episode target prices for participant hospitals. The following steps would be used to calculate different target prices in each performance year for each combination of anchor MS–DRG (469 vs. 470), hip fracture status (with hip fracture vs. without hip fracture), and period during which target prices are applicable within a performance year (episodes initiated January 1 through September 30 vs. October 1 through December 31 each performance year). The output of each step would be used as the input for the subsequent step, unless otherwise noted.

• (1) Calculate historical CJR episode payments for episodes that were initiated during the 3-historical-years (section III.C.4.b.(2) of this final rule) for all CJR eligible hospitals for all Medicare Part A and B services included in the episode. We note that specific PBPM payments may be excluded from historical episode payment calculations as discussed in section III.C.7.d. of this final rule.

• (2) Remove effects of special payment provisions (section III.C.3.a. of this final rule) and normalize for wage index differences (section III.C.4.b.(7) of this final rule) by standardizing Medicare FFS payments at the claim-level.

• (3) Prorate Medicare payments for included episode services that span a period of care that extends beyond the episode (section III.C.3.b of this final rule.).

• (4) Trend forward 2 oldest historical years of data to the most recent year of historical data. As discussed in section III.C.4.b.(3) of this final rule, separate national trend factors would be applied for each combination of anchor MS–DRG (469 vs. 470) and hip fracture status (with hip fracture vs. no hip fracture).

• (5) Cap high episode payment episodes with a region and MS DRG anchor specific high payment ceiling as discussed in section III.C.3.c. of this final rule, using the episode output from the previous step. We have posted region specific historical average episode payments on the CJR final rule Web site at *http://innovation.cms.gov/initiatives/CJR/*.

• (6) Calculate anchor factor and participant hospital specific weights (section III.C.4.b.(8) of this final rule) using the episode output from the previous step to pool together MS DRG 469 and 470 anchored episodes with and without hip fracture, resulting in participant hospital specific pooled historical average episode payments. Similarly, calculate region specific weights to calculate region specific pooled historical average episode payments.

• (7) Calculate participant hospital specific and region specific weighted update factors as described in section III.C.4.b.(4) of this final rule. Multiply each participant hospital specific and region specific pooled historical average episode payment by its corresponding participant hospital specific and region specific weighted update factors to calculate participant hospital specific and region specific updated, pooled, historical average episode payments.

• (8) Blend together each participant hospital specific updated, pooled, historical average episode payment with the corresponding region specific updated, pooled, historical average episode payment according to the proportions described in section III.C.4.b.(5) of this final rule. Participant hospitals that do not have the minimum episode volume across the historical 3 years would use 0.0 percent and 100 percent as the proportions for hospital and region, respectively. For purposes of this final rule, we will define the output of this step as the pre-discount target price for MS DRG 470 anchored episodes without hip fracture.

• (9) Multiply the output of step (8) by the appropriate anchor factors (step (6) of this target price calculation process and detailed in section III.C.4.b.(8) of this final rule) for MS DRG 469 anchored episodes with hip fracture, MS DRG 469 anchored episodes without hip fracture, and MS DRG 470 anchored episodes with hip fracture. For purposes of this final rule, we will define the outputs of this step as the pre-discount target prices for MS DRG 469 anchored episodes with hip fracture, MS DRG 469 anchored episodes without hip fracture, and MS DRG 470 anchored episodes with hip fracture.

• (10) Multiply the pre-discount target prices for MS DRGs 469 and 470 episodes with and without hip fracture by the appropriate effective discount factor that incorporates any quality incentive payment, as briefly described in section III.C.4.b.(9) of this final rule

and more specifically detailed in the response to comments in section III.C.5. of this final rule and Tables 19, 20, and 21. The results of these calculations will be participant hospitals' target prices for MS DRG 469 anchored episodes with hip fracture, MS DRG 469 anchored episodes without hip fracture, MS DRG 470 anchored episodes with hip fracture, and MS DRG 470 anchored episodes without hip fracture.

The previously stated 10 steps will be used to calculate target prices for episodes that begin between January 1 and September 30 (between April 1 and September 30 for performance year 1), as well as for episodes that begin between October 1 and December 31, for each performance year. The target price calculations for the two different time periods each performance year will differ by the update factors used in the seventh step. By following these ten steps, we will calculate target prices for each participant hospital for each performance year. We refer readers to section III.C.4.b. of this final rule for further details on each of the specific steps.

*Final Decision:* After consideration of the public comments we received, we are modifying our proposal to incorporate changes described in sections III.C.3, III.C.4.b, and III.C.5 of this final rule when fitting together and sequencing episode target price features used to calculate CJR episode target prices for participant hospitals.

These final policies are set forth at § 510.300 and § 510.305.

5. Use of Quality Performance in the Payment Methodology

a. Background

Over the past several years Medicare payment policy has moved away from FFS payments unlinked to quality and towards payments that are linked to quality of care. Through the Affordable Care Act, we have implemented specific IPPS programs like the HVBP program (subsection (o) of section 1886 of the Act), the Hospital Acquired Condition Reduction Program (HACRP) (subsection (q) of section 1886) and the HRRP (subsection (p) of section 1886), where quality of care is linked with payment. We have also implemented the Shared Savings Program, an ACO program that links shared savings payment to quality performance. Since the implementation of the HRRP in October 2012, readmission rates for various medical conditions like THA and TKA (THA/TKA) have improved. Trend analyses show a decrease in readmission rates and specifically with THA/TKA risk-standardized readmissions rates (RSRR) from 5.4 percent (July 2010–June 2011) to 4.8 percent (July 2012–June 2013).[41] Additionally, hospital THA/TKA RSCR decreased from 3.4 percent (April 2010 through March 2011) to 3.1 percent (April 2012 through March 2013). Despite the downward trend of THA/TKA RSRRs and RSCRs, the wide dispersion in these readmission rates suggests there is still room for hospitals to improve their performance on these measures as illustrated by a THA/TKA RSRR distribution of 2.8 to 9.4 percent (July 2010–June 2013) and a THA/TKA RSCR distribution of 1.5 to 6.4 percent (April 2010–March 2013). In the proposed rule, we stated our belief that the CJR model would provide another mechanism for hospitals to improve quality of care, while also achieving cost efficiency. Incentivizing high-value care through episode-based payments for LEJR procedures is a primary objective of CJR. Therefore, incorporating quality performance into the episode payment structure is an essential component of the CJR model. We also stated our belief that the financial opportunity discussed in section III.C.2. of the proposed rule would provide the appropriate incentives necessary to reward a participant hospital's achievement of episode savings when the savings are greater than the discounted target price. For the reasons stated previously, we discussed our belief that it would be important for the CJR model to link the financial reward opportunity with achievement in quality of care for Medicare beneficiaries undergoing LEJR.

As discussed in section III.C. of this final rule, which outlines the payment structure proposed for the CJR model, each participant hospital would have target prices calculated for MS–DRG 469 and 470 anchored episodes; each anchored episode would include an anchor hospitalization for an LEJR procedure and a 90–day period after the date of discharge from the anchor hospitalization. These episode target prices represent expected spending for all related Part A and Part B spending for such episodes, with a discount applied. Hospitals who achieve actual episode spending below a target price for a given performance period would be eligible for a reconciliation payment from CMS, subject to the proposed stop-gain limit policy as discussed in section III.C.8. of this final rule.

In the proposed rule, we proposed quality performance standards that must also be met in order for a hospital to be eligible to receive a reconciliation payment under CJR. Specifically, we described our proposal to include a performance measure result threshold on select outcomes-based quality measures as a requirement for participants to receive a reconciliation payment if actual episode spending is less than the target price under CJR in a performance year, in addition to a payment adjustment for successful reporting of a voluntary measure in development. Beginning in performance year one and continuing throughout the duration of the model, we proposed to make reconciliation payments only to those CJR hospital participants that met or exceeded a minimum measure result threshold. We also discussed an alternative approach to determining CJR reconciliation payment eligibility and adjusting payment based on a quality score developed from performance on three outcomes-based quality measures and success in reporting the voluntary measurement in development.

b. Implementation of Quality Measures in the Payment Methodology

In section III.D. of the proposed rule, we proposed three measures to assess quality of care of the hospitals participating in the CJR model. We also proposed voluntary data submission for a patient-reported outcome measure in development. In section III.C.5. of the proposed rule, we proposed using three measures to determine eligibility for a reconciliation payment, as well as proposed rewarding hospitals that voluntarily submit data for the patient-reported outcome measure. We also discussed an alternative approach to determining reconciliation payment eligibility and adjusting payment based on a composite quality score calculated from the three required outcome measures and success on reporting voluntary data on the patient-reported outcome measure.

(1) General Selection of Quality Measures

The CJR model is designed to provide financial incentives to improve coordination of care for beneficiaries that we expect to lead to avoidance of post-surgical complications and hospital readmissions, as well as to improve patient experience through care redesign and coordination. Furthermore, we acknowledge that achievement of savings while ensuring high-quality care for Medicare FFS beneficiaries in LEJR episodes would require close collaboration among hospitals,

[41] Hospital Quality Initiatives. CMS Hospital Quality Chartbook 2014. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf.* Accessed April 21, 2015.

physicians, PAC providers, and other providers and suppliers. In order to encourage care collaboration among multiple providers of patients undergoing THA and TKA, we proposed three measures, as described in detail in section III.D.2. of this final rule, to determine hospital quality of care and to determine eligibility for a reconciliation payment under the CJR model. The measures we proposed are as follows:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (National Quality Forum (NQF)#1551), an administrative claims-based measure.
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550), an administrative claims-based measure.
- HCAHPS Survey measure (NQF #0166).

Beginning in performance year 1 and continuing throughout the duration of the model, we proposed to make reconciliation payments only to those CJR participant hospitals that met or exceeded a minimum performance threshold on the measures previously listed. We proposed that hospitals must meet or exceed the measure reporting thresholds and other requirements described in section III.C.5 and III.D. of this final rule on all three measures in order to be eligible for a reconciliation payment.

These three outcome measures were chosen due to their: (1) Alignment with the goals of the CJR model; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including programs that tie payment to performance such as HVBP and HRRP; and (3) assessment of CMS priorities to improve the rate of LEJR complications and readmissions, while improving patient experience. In the proposed rule, we stated our belief that the three quality measures we proposed for reconciliation payment eligibility reflected these goals and accurately measured hospitals' level of achievement on such goals.

(2) Adjustment to the Payment Methodology for Voluntary Submission of Data for Patient-Reported Outcome (PRO) Measure

During our consideration of quality metrics for the CJR model, we examined the feasibility of linking voluntary data submission of patient-reported outcomes, beyond the current three required measures discussed in section III.D.2. of this final rule for use in the model, with the possibility of incentivizing participant hospitals under the episode payment model to participate in this voluntary submission of data. We specifically examined potential patient-reported outcome measures since this type of outcome measure aligns with the CJR model goal of improving LEJR episode quality of care, including a heightened emphasis on patient-centered care where patients provide meaningful input to their care. Furthermore, the availability of patient reported outcome data would provide additional information on a participant hospital's quality performance, especially with respect to a patient's functional status, beyond the current three required measures discussed in section III.D.2. of this final rule for use in the model. We noted that we have a measure in development, the Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary THA or TKA measure or both (hence forth referred to as ''THA/TKA patient-reported outcome-based measure''), that would support the National Quality Strategy domain of patient and family engagement, and could capture meaningful information that would not otherwise be available on patient outcomes that are related to the quality of LEJR episodes under CJR. In the proposed rule, we stated our belief that incorporating this measure into CJR by adjusting the payment methodology for successful voluntary data submission on the THA/TKA patient-reported outcome-based measure (henceforth referred to as ''THA/TKA voluntary data'') would provide participant hospitals with valuable information on functional outcomes that would assist them in assessing an important patient-centered outcome, engaging other providers and suppliers in care redesign for LEJR episodes, as well as provide them with the potential for greater financial benefit from improved LEJR episode efficiencies. We did not believe it would be appropriate at this time to hold any participant hospitals financially accountable for their actual THA/TKA voluntary data, as we proposed to require for the three measures described in section III.C.5.b.(5) of this final rule.

Instead, we proposed to adjust the episode payment methodology for participant hospitals that successfully submit THA/TKA voluntary data by reducing the discount percentage used to set the target price from 2.0 percent to 1.7 percent of expected episode spending based on historical CJR episode data, hereinafter referred to as the voluntary reporting payment adjustment. The proposed payment policies with respect to reconciliation payment eligibility and the discount percentage based on hospital voluntary data submission are summarized in Table 10 for performance years 3 through 5 where we proposed that hospitals have full repayment responsibility. The proposed specific percentages that would apply for purposes of the repayment amount and reconciliation payment are outlined for performance years 1 and 2 in the discussion that follows.

TABLE 10—PROPOSED RECONCILIATION PAYMENT ELIGIBILITY AND DISCOUNT PERCENTAGE INCLUDED IN THE TARGET PRICE FOR EACH PARTICIPANT HOSPITAL BASED ON QUALITY PERFORMANCE IN PERFORMANCE YEARS 3 THROUGH 5

| Discount percentage included in target price/reconciliation payment eligibility | Meets thresholds for all 3 required quality measures | Does not meet thresholds for one or more of 3 required quality measures |
|---|---|---|
| Successfully submits THA/TKA voluntary data | 1.7%/eligible | 1.7%/ineligible. |
| Does not successfully submit THA/TKA voluntary data | 2.0%/eligible | 2.0%/ineligible. |

We refer readers to section III.D.3.a. of this final rule for further discussion of the THA/TKA patient-reported outcome-based measure and our proposed definition of successful reporting. In addition, we refer readers to section III.C.4.b.(9) of this final rule for discussion of the proposed discount of 2.0 percent (without the voluntary reporting payment adjustment) to establish the target price. In the proposed rule, we stated our belief that a voluntary reporting payment adjustment of 0.3 percent of expected episode spending would, on average, cover the participant hospitals' additional administrative costs of voluntarily reporting patient risk variables and patient-reported reported function for outcome calculation. We estimated the value of this discount

reduction, on average, to be about $75 per LEJR episode at a participant hospital, which we believed would be sufficient to pay hospitals for the resources required to survey beneficiaries pre- and post-operatively about functional status and report this information required for measure development to CMS. We also believed that voluntary reporting on this patient-reported outcome measure would be integral to implementation of the CJR model, as it would allow us to further develop and evaluate the measure for potential use in this model in the future as a measure of quality that is important and not captured in any other available measures.

We proposed that the voluntary reporting payment adjustment would be available for all years of the model, unless we find the measure to be unfeasible or have adequately developed the measure such that continued voluntary data collection is no longer needed for measure development during the course of the model. In those situations, we would notify participant hospitals that the voluntary reporting payment adjustment was no longer available as we would cease collecting the data.

We proposed that when we provide the episode target price to each participant hospital at 2 times during the performance year, we would provide different target prices reflecting the 2.0 percent and 1.7 percent discounts. At the time of reconciliation for the performance year, we would determine which participant hospitals successfully reported the THA/TKA voluntary data for that performance year. The effects of this voluntary reporting payment adjustment would vary for each year of the model, depending on the proposed reconciliation payment and repayment policies for that performance year. For hospitals that achieved successful reporting of the THA/TKA voluntary data in performance year 3, 4, or 5, we would use the target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to calculate the hospital's reconciliation payment or repayment amount. Based on this comparison, consistent with the proposal described in section III.C.6. of this final rule, we would make a reconciliation payment if actual episode spending was less than the target price (and the thresholds for reconciliation payment eligibility are met for the three required quality measures) or make participant hospitals responsible for repaying Medicare if actual episode spending exceeded the target price. For performance year 2, when we proposed that repayment responsibility would be phased-in, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures were met. In order to help hospitals transition to taking on repayment responsibility, we proposed to apply a reduced discount of 0.7 percent for successful THA/TKA voluntary data reporting hospitals (compared with 1.0 percent for nonreporting or unsuccessfully reporting hospitals) in performance year 2 for purposes of determining the hospital's repayment responsibility for excess episode spending. For performance year 1, when we proposed that there would be no repayment responsibility, for participant hospitals with successful THA/TKA voluntary data reporting, we would use a target price reflecting the 1.7 percent discount (compared with the 2.0 percent discount for nonreporting or unsuccessfully reporting hospitals) to determine if actual episode spending was below the target price, whereupon the participant hospital would receive a reconciliation payment if the quality thresholds on the three required measures were met. In the proposed rule, we stated our belief that this proposed voluntary reporting payment adjustment would provide the potential for increased financial benefit for participant hospitals due to a higher target price (that reflects a lower discount percentage) that successfully report the measure. Participant hospitals that successfully reported the voluntary data would be subject to a lower repayment amount (except for performance year 1 when hospitals have no repayment responsibility) or a higher reconciliation payment (assuming the thresholds are met on the three required measures for reconciliation payment eligibility), than hospitals that did not successfully report the voluntary data.

In general, we proposed that participant hospitals that met the performance thresholds for the three required quality measures and reduced actual episode spending below the target price, as well as successfully reported the THA/TKA voluntary data, would be eligible to retain an additional 0.3 percent of the reduced episode expenditures relative to participant hospitals that successfully reported the three required quality measures but did not report voluntary data, funds which would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. Additionally, for performance years 2–5 where we proposed that participant hospitals would have payment responsibility, participant hospitals with increased actual episode spending above the target price would not be required to repay 0.3 percent of the increased episode expenditures (relative to participant hospitals that do not report voluntary data), funds that would offset additional administrative costs that the participant hospitals would incur in reporting on the measure. These costs would include the hospital staff time required for training on the measure, as well as then gathering and reporting on multiple patient risk variables from LEJR episode beneficiaries' medical records and locating beneficiaries and administering via phone survey questions on functional status, which would also then be reported to CMS. Thus, we expected that the proposal would encourage reporting by a number of participant hospitals, and it would have the potential to benefit those hospitals that successfully reported on the measure. Therefore, this proposal could financially benefit reporting hospitals that would also collect valuable information on patient functional outcomes that could inform their LEJR care redesign. While this measure remains in development from our perspective to ensure translation of data across care settings and the respective hospital communities during the 90-day post-discharge episode of care, participant hospitals would gain anecdotal, locally relevant information regarding the patient-reported outcomes of their own patients that could inform participant hospitals' continuous quality improvement efforts.

We considered two alternative options to adjust the CJR payment methodology by modifying the required quality measure thresholds for reconciliation payment eligibility for those participant hospitals that successfully submit the THA/TKA voluntary data. First, we considered adjusting the threshold that hospitals must meet on the three required quality measures for reconciliation payment eligibility if reduced episode spending was achieved from the unadjusted 30th percentile threshold to the adjusted 20th percentile threshold for performance years 1, 2, and 3, and from the unadjusted 40th percentile to the adjusted 30th percentile for performance years 4 and 5. Second, we

considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures for performance years 4 and 5. These options would provide the opportunity for some participant hospitals, specifically those that missed the unadjusted percentile for one or more of the three required quality measures by a specified margin, to receive reconciliation payments if actual episode spending was less than the target price. However, these options could benefit only a subset of participant hospitals that successfully reported the THA/TKA voluntary data. For the majority of participant hospitals that we expect would meet the unadjusted thresholds for all three required measures, these options would not provide any incentive to voluntarily report the data because the hospitals would not benefit from voluntarily reporting the additional measure. We decided not to propose either of these options to adjust the CJR payment methodology for participant hospitals that voluntarily report data on the new measure because the limited benefit could result in few hospitals choosing to report on the measure, thereby limiting our progress in developing the measure. We noted that these two considered options and our proposal were not mutually exclusive.

We sought comment on the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. Given our interest in robust hospital participation in reporting on the THA/TKA voluntary data under CJR, we were specifically interested in information on the additional resources and their associated costs that hospitals would incur to report THA/TKA voluntary data, as well as the relationship of these costs to the potential financial benefit participant hospitals could receive from the proposed reduced discount of 1.7 percent. Based on such information, we would consider whether a change from the proposed discount factor reduction due to successful voluntary data submission would be appropriate. We also sought comment on whether the alternative payment methodology adjustments considered, or combination of adjustments, would more appropriately incentivize CJR participant hospitals to submit THA/TKA voluntary data. In the proposed rule, we stated our belief that development of the THA/TKA patient-reported outcome measure would benefit from reporting by a broad array of participant hospitals, including those that currently deliver high quality, efficient LEJR episode care and those that have substantial room for improvement on quality and or cost-efficiency.

We summarize the public comments we received on the proposed voluntary reporting payment adjustment and provide our responses in section III.C.5.b.(5)(c)(iii) of this final rule. We did not receive public comments on the alternative payment methodology adjustments that we discussed in the proposed rule. Furthermore, in light of our interest in encouraging CJR participant hospital THA/TKA voluntary data reporting, we also considered alternative approaches to collect this information or provide hospitals with funds to help cover their associated administrative costs other than adjustments to the CJR model payment methodology. One alternative would be for hospitals to collect and report on patient pre-operative information collected 0 to 90 days before surgery, while CMS would engage a contractor to collect and report the post-operative information collected 9 to 12 months after surgery. This approach would reduce some of the administrative burden of collection and reporting on hospitals, although participant hospitals would need to provide CMS with certain beneficiary information, including contact information that would be needed for a CMS contractor to contact the beneficiary at a later date. We sought comment on this alternative, including whether hospitals would incur significant additional administrative costs to report on the data prior to surgery and how CMS could best provide funds to offset some of those costs, through an adjustment to the CJR payment methodology or other means. We also sought comment on the information participant hospitals would need to provide to CMS so that a CMS contractor could collect and report the post-operative data, and the most efficient ways for hospitals to provide this information to us. Finally, we considered an approach that would provide hospitals with separate payment outside of an adjustment to the CJR payment methodology to specifically assist in covering their administrative costs of reporting THA/TKA voluntary data, in order to achieve robust hospital participation in reporting. We sought comment on the hospital administrative costs that would be incurred for reporting, as well as on approaches we could take to ensure that hospitals achieved successful reporting under such an approach if separate payment was made. Finally, we expressed our interest in comments regarding the comparative strength of these various alternatives in encouraging hospitals to participate in reporting THA/TKA voluntary data.

We did not receive any public comments on the alternatives we discussed other than adjustments to the payment methodology to collect THA/TKA voluntary data and provide hospitals with funds to cover the required resources. We summarize these comments we received in section III.C.5.b.(5)(c)(iii) of this final rule and provide our responses.

(3) Measure Risk-Adjustment and Calculations

All three proposed outcome measures are risk-adjusted, and we refer readers to section III.D.2. of this final rule for a full discussion of these measures and risk-adjustment methodologies. We believed that risk-adjustment for patient case-mix is important when assessing hospital performance based on patient outcomes and experience and understanding how a given hospital's performance compares to the performance of other hospitals with similar case-mix.

(4) Applicable Time Period

We proposed to use a 3-year rolling performance or applicable period for the Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551) and the Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) measures. We also specifically proposed to align with the HIQR Program's 3-year rolling performance period for the RSRR and RSCR measures since we believed that a 3-year performance period yields the most consistently reliable and valid measure results (FY 2015 IPPS/LTCH final rule, 79 FR 50208 through 50209). For the HCAHPS Survey measure, we proposed to follow the same performance period as in the HIQR Program (FY 2015 IPPS/LTCH final rule, 79 FR 50259). HCAHPS scores are created from 4 consecutive quarters of survey data; publicly reported HCAHPS results are also based on 4 quarters of data. For the voluntary data collection for the proposed THA/TKA patient-reported outcome-based performance measure, the optimal reporting time period had not been determined at the time of issuance of the CJR model proposed rule. Therefore, we proposed defining the applicable time period as

12 month intervals that may begin between July 1, 2016 and December 31, 2016, and continue in subsequent performance years for a total of four or fewer performance periods. Participant hospitals will submit required data to CMS in a mechanism similar to the data submission process for the HIQR Program within sixty days of the end of each 12 month period. As described in section III.C.5.b.(2) of the proposed rule, the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CJR participant hospitals that successfully report on the THA/TKA voluntary data would begin in year 2 and also apply to subsequent years of the model. We are not finalizing the proposed voluntary reporting payment adjustment, as discussed further in section III.C.5.b.(5)(c)(iii) of this final rule. We note that we summarize the public comments we received on the proposed applicable time period and provide our responses in section III.D.3.d. of this final rule, and we summarize the public comments we received on the reporting time period for the THA/TKA patient-reported outcome and limited risk variable data and provide our responses in section III.D.3.a.(9) of this final rule.

(5) Criteria for Applicable Hospitals and Performance Scoring

(a) Identification of Participant Hospitals for the CJR Model

As discussed in section III.A.2. of this final rule, all CJR participant hospitals will be IPPS hospitals.

(b) Methodology To Determine Performance on the Quality Measures

To determine performance on the quality measures, we proposed to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2. of this final rule. Performance on the three measures for the CJR model participant hospitals would be compared to the national distribution of measure results for each of these measures obtained through the HIQR Program. The HIQR Program is an IPPS program in which public reporting is a focus of the program for the nation's acute care hospitals, and we proposed using the absolute value of the CJR model participant hospital's result to determine if that participant hospital was eligible for a reconciliation payment. In essence, we intended to take the HIQR Program measure results (also posted publicly) for the proposed measures, identify the proposed threshold, and apply the thresholds as outlined in section III.C.5.b.(5)(c)(iii) of this final rule. In the proposed rule, we stated our belief that it would be reasonable to use the HIQR Program distribution of measure results to identify a measure result threshold because—(1) The hospitals in the HIQR Program represent most acute care hospitals in the nation; (2) the CJR model participant hospitals are a subset of the hospitals in the HIQR Program; and (3) the expectation that the CJR model participant hospitals meet a measure result threshold based on a national distribution of measure results would encourage the CJR model participant hospitals to strive to attain measure results consistent with or better than hospitals across the nation. For a detailed description of how we proposed to determine the measure result thresholds for consideration of a reconciliation payment adjustment, see section III.C.5.b.(3) and III.C.5.b.(5)(c) of this final rule. We would not want to encourage CJR model participant hospitals to strive for measure results or quality of care performance that may be lower than the national measure results. Given that the CJR participant hospitals are a subset of the HIQR Program participant hospitals, they are familiar with these three measures and may have put into place processes that will help to improve quality of care in the LEJR patient population. Finally, once the measure results were calculated, we proposed to use these results to determine eligibility for reconciliation payment, which is discussed in detail in the next section.

We summarize the public comments we received on the proposed calculation of the measure results and application of performance thresholds and provide our responses in sections III.D.2 and III.C.5.b.(5)(c)(iii) of this final rule, respectively.

To be considered to have successfully reported the voluntary data collection and submission for the THA/TKA voluntary data, we proposed that successfully reporting would mean participant hospitals must meet all of the following:

- Submit the data elements listed in section III.D.3.a.(2) of this final rule.
- Data elements listed in section III.D.3.a.(3) of this final rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients (patients eligible for pre-operative THA/TKA voluntary data submission are those described in section III.D.3.a.(3) of this final rule); patients eligible for post-operative THA/TKA voluntary data submission are those described in section III.D.3.a.(3) of this final rule and also having a THA/TKA procedure date during the anchor hospitalization at least 366 days prior to the end of the data collection period. Therefore, participant hospitals would not be expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent performance period.

Hospitals that meet these three standards and successfully submit THA/TKA voluntary data would be eligible for the proposed voluntary reporting payment adjustment of reducing the discount percentage from 2.0 percent to 1.7 percent for CJR participant hospitals that voluntarily and successfully report on the THA/TKA voluntary data. We note that we are not finalizing this voluntary reporting payment adjustment proposal as discussed in section III.C.5.b.(5)(c)(iii) of this final rule. However, we continue to believe that encouraging collection and submission of the THA/TKA voluntary data through the CJR model would increase availability of patient-reported outcomes to both participant hospitals that collect and submit data on their own patients in the model (and their patients as well); further development of an outcomes measure that provides meaningful information on patient-reported outcomes for THA/TKA procedures that are commonly furnished to Medicare beneficiaries; provide another quality measure that may be incorporated into the CJR model policy linking quality to payment in future performance years, pending successful development of the measure; and inform the quality strategy of future payment models. Collecting data on at least 80 percent of hospital's eligible THA/TKA patients would provide sufficiently representative data to allow for development and testing of the THA/TKA patient-reported outcome-based performance measure.

We invited public comment on the proposal to calculate measure results for all three measures as outlined in the Quality Measures section III.D.2. of this final rule. We also sought public comment on our proposal for hospitals to meet three requirements, previously outlined, in order to be considered as successfully submitting THA/TKA voluntary data.

We summarize the public comments on the proposals to calculate measure results and determine measure result thresholds and provide our responses in sections III.D.2. and III.C.5.b.(5)(c)(iii) of this final rule, respectively. We summarize the public comments on the proposals for successful THA/TKA

voluntary data submission and provide our responses in section III.D.3.a. of this final rule.

(c) Methodology To Link Quality and Payment

(i) Background

In proposing a methodology for linking payment for LEJR episodes to quality under this model, we considered several alternatives. Specifically, we considered making reconciliation payments to hospitals tied to achievement and improvement in quality performance or, alternatively, establishing minimum quality performance thresholds for selected quality measures from the beginning of the model or a later year, which would reward achievement but not necessarily improvement. While we proposed as discussed section III.C.5.b.(5)(c) of this final rule to establish minimum thresholds for participant hospital performance on three selected quality measures for reconciliation payment eligibility each performance year from the beginning of the model, we also discussed in detail an alternative we considered, which would make quality incentive payments related to hospital achievement and improvement on the basis of a composite quality score developed for each performance year. The composite quality score would affect reconciliation payment eligibility and change the effective discount included in the target price experienced by a participant hospital at reconciliation.

Similar to the proposal described in section III.C.5.b.(5)(c) of this final rule, the alternatives considered would require a determination of participant hospital performance on all three proposed required quality measures, described in section III.D.2. of this final rule, based on the national distribution of hospital measure result performance, but instead of identifying the participant hospital's performance percentile for comparison with a threshold requirement, we would do so for purposes of assigning points toward a hospital composite quality score. Both the hospital-level 30-day, all cause Risk-Standardized Readmission Rate (RSRR) following elective primary THA and/or TKA (NQF #1551) measure and the hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA and/or TKA (NQF #1550) measure directly yield rates for which a participant hospital performance percentile could be determined and compared to the national distribution in a straightforward manner. As discussed in section III.D.2.c. of this final rule, we proposed to use the HCAHPS Linear Mean Roll Up (HLMR) score calculated using the HCAHPS Survey measure (NQF #0166). Once the HLMR scores are calculated, the participant hospital performance percentile could also be determined and compared to the national distribution in a straightforward manner. In addition, the alternatives considered would account for the successful submission of voluntary THA/TKA data on the patient-reported outcome measure, as discussed in section III.C.5.b.(2) of this final rule, in the calculation of the composite quality score.

(ii) Alternatives Considered To Link Quality and Payment

We considered assigning each participant hospital a composite quality score, developed as the sum of the individual quality measure scores described later in this section, which were set to reflect the intended weights for each of the quality measures and the successful submission of THA/TKA voluntary data in the composite quality score. The participant hospital's composite quality score would affect reconciliation payment eligibility and could also provide the opportunity for quality incentive payments under the CJR model. Each quality measure would be assigned a weight in the composite quality score and possible scores for the measures would be set to reflect those weights. A composite quality score for each performance year would be calculated for each participant hospital based on its own performance that would affect reconciliation payment eligibility and the hospital's opportunity to receive quality incentive payments under the model. The composite quality score would also change the effective discount included in the target price experienced by the hospital at reconciliation for that performance year. We would weigh participant hospital performance on each of the three measures and successful submission of voluntary THA/TKA data according to the measure weights displayed in Table 11.

TABLE 11—QUALITY MEASURE WEIGHTS UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

| Quality measure | Weight in composite quality score (%) |
|---|---|
| Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551) | 20 |
| Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) | 40 |
| HCAHPS Survey (NQF #0166) | 30 |
| Voluntary THA/TKA data submission on patient-reported outcome measure | 10 |

We would assign the lowest weight of 10 percent to the successful submission of THA/TKA data on the patient-reported outcome measure because these data represent a hospital's meaningful participation in advancing the quality measurement of LEJR patient-reported outcomes but not actual outcome performance for LEJR episodes under the CJR model. In the proposed rule, we stated our belief the three required measures that represent LEJR outcomes deserve higher weights in the composite quality score. We would assign a modest weight of 20 percent to the readmissions measure because, while we believed that readmissions are an important quality measure for LEJR episodes, the episode payment methodology under the model already provides a strong financial incentive to reduce readmissions that otherwise would contribute significantly to greater actual episode payments. Furthermore, hospitals generally have already made significant strides over the past several years in reducing readmissions due to the inclusion of this measure in other CMS hospital programs that make payment adjustments based on performance on this measure. We believed that a higher weight than 20 percent would overvalue the contribution of readmissions performance as an indicator of LEJR episode quality in calculating the composite quality score. Furthermore, other CMS hospital programs may also make a payment adjustment based on hospital performance on the readmissions measure, so we would not want this measure to also strongly influence reconciliation payment eligibility and the opportunity for quality incentive payments under the

CJR model. We would assign a higher weight of 30 percent to the HCAHPS Survey measure because we believed that incorporating this quality measure, which reflects performance regarding patients' perspectives on care, including communication, care transitions, and discharge information, is a highly meaningful outcome measure of LEJR episode quality under the CJR model. However, we did not believe it would be appropriate assign the HCAHPS Survey measure the highest weight of the four measures, as the measure is not specific to LEJR episode care, but rather to all clinical conditions treated by participant hospitals. Finally, we would assign the highest weight, 40 percent, to the complications measure. We believed this measure should be weighted the most because it is specific to meaningful outcomes for primary THA and TKA that are the major procedures included in LEJR episodes under the CJR model. The measure includes important complications of LEJR episodes, such as myocardial infarction, pneumonia, surgical site bleeding, pulmonary embolism, death, mechanical joint complications, and joint infections occurring within various periods of time during the LEJR episode. LEJR episodes under the CJR model are broadly defined so that reducing complications should be a major focus of care redesign that improves quality and efficiency under this model, yet because complications may not be as costly as readmissions, the payment incentives under the model would not as strongly target reducing complications as reducing readmissions. We sought comment on this weighting of the individual quality scores in developing a composite quality score for each participant hospital.

Under such an approach, we would first score individually each participant hospital on the Hospital-level 30-day, all-cause RSRR using the elective primary THA and/or TKA (NQF #1551) measure; Hospital-level RSCR following using the elective primary THA and/or TKA measure (NQF #1550); and HCAHPS Survey measure (NQF #0166) based on the participant hospital's performance percentile as compared to the national distribution of hospitals' measure performance, assigning scores according to the point values displayed in Table 12. These individual measure scores were set to reflect the measure weights included in Table 11 so they could ultimately be summed without adjustment in calculating the composite quality score.

TABLE 12—INDIVIDUAL SCORING UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED FOR THREE REQUIRED QUALITY MEASURES IN THE PROPOSED RULE

| Performance percentile | Complications measure quality score (points) | HCAHPS survey quality score (points) | Readmissions measure quality score (points) |
|---|---|---|---|
| ≥90th | 8.00 | 6.00 | 4.00 |
| ≥80th and <90th | 7.40 | 5.55 | 3.70 |
| ≥70th and <80th | 6.80 | 5.10 | 3.40 |
| ≥60th and <70th | 6.20 | 4.65 | 3.10 |
| ≥50th and <60th | 5.60 | 4.20 | 2.80 |
| ≥40th and <50th | 5.00 | 3.75 | 2.50 |
| ≥30th and <40th | 4.40 | 3.30 | 2.20 |
| <30th | 0.00 | 0.00 | 0.00 |

Given the current national distribution of hospital performance on these measures, in the proposed rule we stated our belief that small point increments related to higher measure performance deciles would be the most appropriate way to assign more points to reflect meaningfully higher quality performance on the measures. The absolute differences for each decile among the three measures reflect the intended weight of the measure in the composite quality score. We would assign any low volume participant hospital without a reportable value for the measure to the 50th performance percentile of the measure, so as not to disadvantage a participant hospital based on its low volume alone because that hospital may in actuality provide high quality care. These three measures are well-established measures in use under CMS hospital programs, so we did not believe that scores below the 30th percentile reflect quality performance such that they should be assigned any individual quality measure score points for LEJR episodes under CJR. However, we also considered reducing scores incrementally across the bottom three deciles in order to provide greater incentives for quality improvement for hospitals that may not believe they can attain the 30th performance percentile on one or more of the three measures and to avoid creating a ''cliff'' at the 30th performance percentile. We sought comment on this scoring approach to the three required quality measures.

Additionally, we would assign a measure quality score of one point for participant hospitals that successfully submit THA/TKA voluntary data and 0 points for participant hospitals that do not successfully submit these data. Because we would not use the actual THA/TKA voluntary data on the patient-reported outcome measure in assessing LEJR episode quality performance under the model, we believed this straightforward binary approach to scoring the submission of THA/TKA voluntary data for the patient-reported outcome measure development would be appropriate.

We note that the Shared Savings Program utilizes a similar scoring and weighting methodology, which is described in detail in the CY2011 Shared Savings Program Final Rule (see § 425.502). The HVBP and HACRP programs also utilize a similar scoring methodology, which applies weights to various measures and assigns an overall score to a hospital (79 FR 50049 and 50102).

We would sum the score on the three quality measures and the score on successful submission of THA/TKA voluntary data to calculate a composite quality score for each participant hospital. Then we would incorporate this score in the model payment methodology by first, requiring a minimum composite quality score for reconciliation payment eligibility if the participant hospital's actual episode spending is less than the target price and second, by making quality incentive payments that change the effective discount percentage included in the target price experienced by the hospital in the reconciliation process. The payment policies we would apply are displayed in Tables 13, 14, and 15 for the performance years of the model.

Under the CJR model as proposed, there would be no participant hospital repayment responsibility in performance year 1 and this responsibility would begin to be phased-in in performance year 2, with full implementation in performance year 3.

TABLE 13—PERFORMANCE YEAR 1: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

| Composite quality score | Eligible for reconciliation payment | Eligible for quality incentive payment | Effective discount percentage for reconciliation payment (%) | Effective discount percentage for repayment amount |
|---|---|---|---|---|
| ≤5.00 | No | No | 3.0 | Not applicable. |
| >5.00 and ≤9.25 | Yes | No | 3.0 | Not applicable. |
| >9.25 and ≤15.20 | Yes | Yes | 2.0 | Not applicable. |
| >15.20 | Yes | Yes | 1.5 | Not applicable. |

TABLE 14—PERFORMANCE YEAR 2: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

| Composite quality score | Eligible for reconciliation payment | Eligible for quality incentive payment | Effective discount percentage for reconciliation payment (%) | Effective discount percentage for repayment amount (%) |
|---|---|---|---|---|
| ≤5.00 | No | No | 3.0 | 2.0 |
| >5.00 and ≤ 9.25 | Yes | No | 3.0 | 2.0 |
| >9.25 and ≤ 15.20 | Yes | Yes | 2.0 | 1.0 |
| >15.20 | Yes | Yes | 1.5 | 0.5 |

TABLE 15—PERFORMANCE YEARS 3–5: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION UNDER THE COMPOSITE QUALITY SCORE ALTERNATIVE CONSIDERED IN THE PROPOSED RULE

| Composite quality score | Eligible for reconciliation payment | Eligible for quality incentive payment | Effective discount percentage for reconciliation payment (%) | Effective discount percentage for repayment amount (%) |
|---|---|---|---|---|
| ≤5.00 | No | No | 3.0 | 3.0 |
| >5.00 and ≤ 9.25 | Yes | No | 3.0 | 3.0 |
| >9.25 and ≤ 15.20 | Yes | Yes | 2.0 | 2.0 |
| >15.20 | Yes | Yes | 1.5 | 1.5 |

Under this approach, the CJR model discount included in the target price without consideration of the composite quality score would be 3.0 percent, not the 2.0 percent described under our payment proposal in section III.C.4.b.(9) of this final rule. In the proposed rule, we stated our belief that a discount percentage of 3.0 percent without explicit consideration of episode quality is reasonable as it is within the range of discount percentages included in the ACE demonstration and it is the Model 2 BPCI discount factor for 30 and 60 day episodes, where a number of BPCI participants are testing LEJR episodes subject to the 3.0 percent discount factor. Hospitals that provide high quality episode care would have the opportunity to receive quality incentive payments that would reduce the effective discount percentage as displayed in Tables 13, 14, and 15. Depending on the participant hospital's actual composite quality score, quality incentive payments could be valued at 1.0 percent to 1.5 percent of the hospital's benchmark episode price (that is, of the expected episode spending prior to application of the discount factor to calculate a target price).

Under this methodology, we would require hospitals to achieve a minimum composite quality score of greater than 5.00 to be eligible for a reconciliation payment if actual episode spending was less than the target price. Participant hospitals with below acceptable quality performance reflected in a composite quality score less than or equal to 5.00 would not be eligible for a reconciliation payment if actual episode spending was less than the target price. A level of quality performance that is below acceptable would not affect participant hospitals' repayment responsibility if actual episode spending exceeds the target price. We believed that excessive reductions in utilization that lead to low actual episode spending and that could result from the financial incentives of an episode payment model would be limited by a requirement that this minimum level of LEJR episode quality be achieved for reconciliation payments to be made. This policy would encourage hospitals to focus on appropriate reductions or changes in utilization to achieve high quality care in a more efficient manner. Therefore, these hospitals would be ineligible to

receive a reconciliation payment if actual episode spending was less than the target price.

For hospitals with composite quality scores of less than or equal to 5.00, we also considered a potential alternative approach. Under this approach, we would still permit this group of hospitals to receive reconciliation payments but would impose a quality penalty that would increase their effective discount percentage to 4.0 percent for purposes of calculating the reconciliation payment or recoupment amount in performance years 3 through 5, 4.0 percent for calculating the reconciliation payment and 3.0 percent for calculating the repayment amount in performance year 2, and 4.0 percent for calculating the reconciliation payment in performance year 1 where participant hospitals have no repayment responsibility. A potential advantage of this approach is that it would provide stronger incentives for quality improvement for participant hospitals with low performance on quality, even if they did not expect to be able to reduce actual episode spending below the target price. In addition, this approach would provide financial incentives to improve the efficiency of care even for hospitals that did not expect to meet the minimum quality score for reconciliation payment eligibility, while still providing strong incentives to provide high-quality care. The disadvantage of this approach is that it could provide reconciliation payments even to hospitals that did not achieve acceptable quality performance.

Participant hospitals with an acceptable composite quality score of >5.00 and ≤9.25 would be eligible for a reconciliation payment if actual episode spending was less than the target price because their quality performance was at the acceptable level established for the CJR model. They would not be eligible for a quality incentive payment at reconciliation because their episode quality performance, while acceptable, was not good or excellent. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price.

Participant hospitals with a good composite quality score of >9.25 and ≤15.20 would be eligible for a quality incentive payment at reconciliation if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they would be eligible for a quality incentive payment at reconciliation for good quality performance that equals 1.0 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Finally, hospitals with an excellent composite score quality score of >15.20 would be eligible to receive a reconciliation payment if actual episode spending was less than the target price because their quality performance exceeded the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they would be eligible for a higher quality incentive payment at reconciliation for excellent quality performance that equals 1.5 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR would either have less repayment responsibility (that is, the quality incentive payment would offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals would be eligible to receive a reconciliation payment if actual episode spending was less than the target price and would also receive a quality incentive payment.

Under this methodology, the proposed stop-loss and stop-gain limits discussed in section III.C.8. of this final rule would not change. We believed this approach to quality incentive payments based on the composite quality score could have the effect of increasing the alignment of the financial and quality performance incentives under the CJR model to the potential benefit of participant hospitals and their collaborators as well as CMS, although it would substantially increase the complexity of the methodology to link quality and payment. We sought comment on this alternative approach to basing reconciliation payment eligibility and quality incentive payments on the participant hospital's composite quality score under the CJR model, as well as the composite quality scoring ranges applicable to the respective payment policies.

While we described in detail this alternative considered to link quality to payment under CJR, we did not propose this methodology for several reasons. First, the Shared Savings Program and HVBP program utilize many more measures than we proposed for the CJR model. For example, the Shared Savings Program initially incorporated thirty-three measures across four quality domains (79 FR 67916 and 67917). The range of measures in the Shared Savings Program and the HVBP program lends itself to a scoring approach, which can account for many measures and allows providers to achieve a high score despite performing well on some measures but achieving lower performance on others. There is a detailed description of the Shared Savings Program scoring methodology on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Quality_Measures_Standards.html*. We believed that given the more limited set of measures chosen for the CJR model, a scoring approach such as the alternative described in this section could diminish the importance of each measure. Use of a scoring approach would not allow hospital performance on two different outcomes to be easily reviewed and understood with respect to the impact of individual measure performance on Medicare's actual payment for the episode under the model. Second, we believed the measures proposed for this model represent goals of clinical care that should be achievable by all hospitals participating in the model that heighten their focus on these measures, especially the readmissions and complications measures, for LEJR episodes based on the financial incentives in the model. Finally, we believed that a methodology that assesses performance based on absolute values of a specific set of measures that

are already in use, as we proposed for the CJR model, would be the most appropriate methodology to provide achievable and predictable quality targets for participant hospitals on measures that monitor the most meaningful quality of care outcomes in a model where some acute care hospitals that might not choose to participate in a voluntary model are also included. Our proposed method as discussed in the next section reflected our expectation that hospitals achieve a certain level of performance on measures to ensure that hospitals provide high-quality care under the model.

Finally, we also considered an approach whereby participant hospitals would not be penalized with regard to their eligibility for reconciliation payments in CJR for failure to meet the specified thresholds for the quality measures in performance year 1 of the model; in other words, we would delay the proposal described in the next section to performance year 2 rather than beginning in performance year 1. We considered calculating participant hospital performance on the required measures for the model, and, if actual episode spending was less than the target price, the participant hospital would receive a full reconciliation payment of savings achieved beyond the target price, regardless of performance on the quality measures. However, we did not believe this would be appropriate for the CJR model, given that two of the measures are administrative claims-based and thus impose no additional reporting burden on hospitals; rather, these two measures are established measures in existing CMS quality programs, and a central goal of the model is improving care for Medicare beneficiaries in LEJR episodes. We noted that the HCAHPS Survey measure (NQF #0166) is also an established measure in the HIQR Program and would not impose additional reporting burden on hospitals.

We summarize the public comments we received on these alternatives considered to link quality and payment and provide our responses in section III.C.5.b.(5)(c)(iii) of this final rule. We note that we will be adopting the composite score methodology for the CJR model, as discussed in our responses to comments in section III.C.5.b.(5)(c)(iii) of this final rule.

(iii) Threshold Methodology and Final Policy To Link Quality and Payment

For the reasons outlined in the previous section, we did not propose to use similar methodologies to other CMS programs that would tie CJR episode reconciliation payment eligibility and reconciliation payment and Medicare repayment amounts to a composite quality score on specified quality measures, but as discussed later in this section, we instead proposed to simply assess performance or achievement on a quality measure by setting a measure result threshold for each measure beginning in performance year 1 of the model.

We proposed that the CJR measure result threshold would be based on the measure results from the HIQR Program, a nationally-established program, and would use its national distribution of measure results. These are the same measure results posted on *Hospital Compare* or in the *Hospital Compare* downloadable database (*https://data.medicare.gov/data/hospital-compare*) for the HIQR Program. We refer readers to the earlier discussion of the HIQR Program, which utilizes measures to assess most acute care hospitals in the nation. Determining the CJR model target thresholds are discussed in the next section.

As previously described, we proposed for the CJR model the following three required measures to assess LEJR episode quality of care:

- Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551).
- Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550).
- HCAHPS Survey (NQF #0166).

We also proposed to make a voluntary reporting payment adjustment for CJR participant hospitals who successfully and voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure (henceforth referred to as ''THA/TKA voluntary data'') as described in sections III.C.5.b.(2) and III.D.3.a. of this final rule. We proposed that participant CJR hospitals must meet or surpass a specified threshold for each required measure beginning for performance year 1 of the model in order to be eligible for a reconciliation payment if actual episode payments are less than the target price. The calculation of the HCAHPS Survey measure is described in section III.D.2.c. of this final rule. We proposed to use the individual measure results calculated as specified in section III.D. of this final rule for the three required measures to determine hospital eligibility for reconciliation payment for each performance year of the CJR model. Also, as discussed in section III.C.4. of this final rule, which outlines the proposed pricing structure for the CJR model, target prices for MS–DRG 470-anchored episodes and for MS–DRG 469-anchored episodes would be calculated for hospitals participating in the model for an episode of care extending 90 days after discharge from the anchor hospitalization. Participant hospitals that achieve actual episode payment below the specified target price for a given performance period would be eligible for a reconciliation payment, provided that the participant hospital also met episode quality thresholds on the three required measures for the performance period.

We proposed to use the following quality criterion to determine if a participant hospital qualifies for a reconciliation payment based on the episode quality thresholds on the three required measures:

The hospital's measure result is at or above the 30th percentile of the national hospital measure results calculated for all HIQR-Program participant hospitals for each of the three required measures for each performance period (for a detailed description of how we determined the performance period and reconciliation payment eligibility, see section III.C.5. of this final rule).

Using HIQR Program's 3 year rolling period as outlined in section III.D.2.d. (Applicable Time Period) of this final rule, if a participant hospital performed at or above the 30th percentile of all HIQR Program hospitals for each of the three required measures and if actual episode payment was less than the target price for the specified performance year, we would make a reconciliation payment to the hospital. Failure to achieve the threshold on one or more measures would result in the participant hospital not receiving a reconciliation payment regardless of whether the actual episode payment was less than the target price for that performance period. We proposed that for hospitals with insufficient volume to determine performance on an individual measure, these hospitals would be considered to be performing at the threshold level and their results would be publicly posted with all other participant hospitals' measure results (for a detailed summary of public reporting, see section III.D.5. of this final rule). We did not believe it would be appropriate to potentially penalize high quality, efficient hospitals due to their low volume, given that meeting the required quality measure thresholds would be required for reconciliation payment eligibility.

We also proposed for performance years 4 and 5 to increase the measure result threshold to the 40th percentile. We believed that increasing the measure result threshold to the 40th percentile

would encourage participants to strive for continued quality improvement throughout the 5 performance years of the model. We sought comment on our proposal to make a reconciliation payment to a participant hospital that achieves actual episode spending below the target price for a performance year and performs at or above the 30th percentile of HIQR program participant hospitals for all three required quality measures in performance years 1 through 3 or the 40th percentile in performance years 4 and 5, as well as our proposal to consider low volume hospitals to be performing at the threshold level.

We proposed to require hospitals to meet the threshold for all three measures for the following reasons. The measures proposed for this model are fully developed, NQF-endorsed, and implemented measures in CMS IPPS programs. These measures are also publicly reported on the *Hospital Compare* Web site. Hospitals are familiar with the complications and readmissions quality measures and with the HCAHPS Survey, as they are currently included in the HIQR Program, HVBP program, and HRRP (79 FR 50031, 50062, 50208, 50209 and 50259), and we believed that there would be minimal additional administrative burden for hospitals. All three measures are widely utilized nationally; thus, a nationally-based threshold would be an appropriate benchmark. In addition, the goal of the CJR model is LEJR episode care redesign that includes effective care coordination and management of care transitions. Strategies to prevent and efficiently manage post-procedure complications and hospital readmissions following an LEJR procedure are consistent with the goals of the model; a hospital cannot succeed in this model without engaging in care redesign efforts that would address aspects of care included in these measures. Failure to perform successfully on these key quality measures (defined by meeting the minimum thresholds) would indicate that hospitals are not achieving quality consistent with the goals of the model to specifically incentivize greater improvement on these measures than hospitals not participating in the CJR model, and should not be eligible to receive a reconciliation payment from Medicare even if reduced episode spending is achieved. Finally, the approach we proposed is consistent with CMS' goal of moving hospitals and other providers to value-based payment that ties payment to quality. In the 5 performance years of this model, performance on quality measures would only be applied to determining eligibility for a reconciliation payment; quality measures would not be used to determine participant hospitals' financial responsibility, except for the proposed voluntary reporting payment adjustment described in described in section III.C.5.b.(3) of this final rule. In essence, participant hospitals' responsibility to repay Medicare the difference between their target price and their actual episode payment, should actual episode payments exceed the target price, would not be impacted by performance on quality measures.

Finally, we proposed to increase the measure result thresholds for the final 2 performance years of the model, to ensure that CJR participant hospitals continue to maintain a high level of quality performance or improve performance on these measures as they gain experience with implementation of this payment model. More specifically, we proposed that in order for a participant hospital to receive a reconciliation payment for actual episode spending that is less than the target price for performance years 4 and 5, the participant hospital's measure result must be at or above the 40th percentile of the national hospital measure results calculated for all HIQR-Program participant hospitals for each of the three required measures for each performance period. As previously noted, we proposed to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR. In the proposed rule, we stated our belief that holding the participant hospitals to a set measure result threshold for the first 3 years, and increasing this threshold for performance years 4 and 5, would emphasize the need to maintain and improve quality of care while cost efficiencies are pursued. We sought comment on our proposed approach to incorporating quality performance into eligibility for reconciliation payments under the CJR model for participant hospitals.

Table 16 displays the proposed thresholds that participant hospitals must meet on the various measures over the 5 model performance years.

TABLE 16—PROPOSED THRESHOLDS FOR REQUIRED QUALITY MEASURES TO DETERMINE PARTICIPANT HOSPITAL RECONCILIATION PAYMENT ELIGIBILITY OVER 5 YEARS

| Measure | PY1 Threshold | PY2 Threshold | PY3 Threshold | PY4 Threshold | PY5 Threshold |
|---|---|---|---|---|---|
| Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551). | 30th percentile ..... | 30th percentile ..... | 30th percentile ..... | 40th percentile ..... | 40th percentile. |
| Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550). | 30th percentile ..... | 30th percentile ..... | 30th percentile ..... | 40th percentile ..... | 40th percentile. |
| HCAHPS Survey (NQF #0166) ..... | 30th percentile ..... | 30th percentile ..... | 30th percentile ..... | 40th percentile ..... | 40th percentile. |

We sought comment on our proposed methodology to utilize quality measure performance in the payment methodology for CJR, as well as the proposed thresholds for participant hospital reconciliation payment eligibility over the performance years of the model.

As discussed in section III.C.5.b.(2) of this final rule, we stated our belief that hospitals that choose to submit THA/TKA voluntary data should have the potential to benefit financially through an adjustment to the payment methodology of the model. We proposed a voluntary reporting payment adjustment for hospitals that successfully submit the THA/TKA voluntary data by reducing the discount percentage incorporated into the target price from 2.0 percent to 1.7 percent. This voluntary reporting payment adjustment would start in performance year 1 and would be available through performance year 5 of the model for each year that the hospital successfully reports THA/TKA voluntary data. As proposed, reporting THA/TKA voluntary data would not affect eligibility for a reconciliation payment if actual episode payments are less than the target price. Participant hospitals would still need to meet the 30th or 40th percentile threshold, as applicable to the given performance year, on all

three required quality measures (Table 16).

We considered, but did not propose, two other alternatives to adjust the payment methodology for participant hospitals that successfully report the THA/TKA voluntary data as described in section III.C.5.b.(2) of this final rule. These alternatives would change the threshold percentile for the three required quality measures or, alternatively, reduce the number of required measures in which the threshold must be met provided that successful THA/TKA voluntary data were reported for a performance year. First, we considered reducing the threshold for reconciliation payment eligibility that participant hospitals must meet on the three required quality measures from the 30th percentile threshold to the 20th percentile threshold for performance years 1, 2, and 3, and from the 40th percentile to the 30th percentile for performance year. Second, we considered only requiring hospitals to meet the 30th percentile threshold on two of three outcome measures for performance years 1, 2, and 3, and the 40th percentile threshold on two of three outcome measures in performance years 4 and 5. Under both of these alternatives, the eligibility for reconciliation payments could change based on the THA/TKA voluntary data. We sought comment on these alternative payment methodology adjustments that could impact reconciliation payment eligibility, unlike the proposed voluntary reporting payment adjustment. We note that the other alternative approaches to encouraging THA/TKA voluntary data reporting for CJR beneficiaries as discussed in section III.C.5.b.(2) of this final rule that would not require adjustments to the CJR payment methodology would also not affect reconciliation payment eligibility.

The following is a summary of the comments received and our responses on the proposals and alternatives discussed in section III.C.5. of the proposed rule, including the proposed threshold methodology for reconciliation payment eligibility, as well as the alternatives considered that would change the proposed threshold requirements for participant hospitals that successfully report voluntary THA/TKA data. As cross-referenced several times earlier in this section, these comments and our responses also discuss a number of other proposals, alternatives considered, and other topics related to linking quality and payment under the CJR model for which we sought public comment.

*Comment:* Some commenters questioned the rationale for linking quality to episode payment for participant hospitals under the CJR model, arguing that the model should not be focused on individual hospital performance but on the overall performance of hospitals within the model, with respect to both the cost and quality of LEJR episode performance. The commenters observed that BPCI, a bundled payment model that includes LEJR as the most commonly selected episode and shares many features with the proposed CJR model, does not tie payment to quality, although BPCI has quality reporting requirements. They claimed that CMS, hospitals, and other providers lack experience with pay-for-performance in a bundled payment context and, therefore, that the level of performance that should be expected from providers under bundled payment is not yet understood. A commenter urged CMS to focus on the big picture in the CJR model, specifically changes in critical aspects of performance versus the national average for all hospitals along the continuum, potential changes in the types or nature of services to beneficiaries undergoing LEJR procedures, and aggregate changes in patient outcomes. Commenters asserted that tying a hospital's payment to performance on quality measures was not the only or the best way to make maintaining or improving LEJR episode quality performance central to the CJR model. Several commenters stated that implementing pay-for-performance in an episode payment model was premature, and recommended that CMS, at most, adopt a pay-for-reporting methodology while quality data are being collected and analyzed to determine the appropriate level of quality performance that should be specifically rewarded.

Several commenters urged CMS to delay implementing the proposed quality performance thresholds for reconciliation payment eligibility until performance year 2, or later, where the performance period for measure data would correspond more fully or completely to performance years under the model. They recommended that the first year or two of the CJR model should be pay-for-reporting and, because the proposed THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) are claims-based measures and the HCAHPS Survey measure (NQF #0166) is currently administered by hospitals, all participant hospitals would be expected to meet the CJR model quality performance requirements, which would only require public reporting in performance year 1 and possibly performance year 2. Several commenters in favor of pay-for-reporting in the first performance year asserted that such an approach would be consistent with other CMS value-based initiatives. A commenter also claimed that a year of pay-for-reporting would allow participant hospitals the time to establish internal systems for analyzing quarterly claims data and provide them with maximal opportunity to achieve savings that could be invested in these systems.

*Response:* We note that we currently have broad experience with pay-for-performance in Medicare programs, including the HRRP, HVBP Program, HAC Reduction Program, and the Shared Savings Program. These pay-for-performance programs have improved the quality of care for Medicare beneficiaries. For example, since the implementation of HRRP in 2012, readmission and complications rates for various medical conditions such as elective THA/TKA have been significantly reduced, thereby resulting in improvements in the quality of care for Medicare beneficiaries undergoing LEJR procedures. Furthermore, pay-for-performance is a feature of a number of Innovation Center models currently in testing. We refer readers to section III.D.5. of this final rule for further discussion of public reporting of pay-for-performance data during performance year 1 of the model.

While the current BPCI models do not specifically link payment to quality, the Request for Applications describing the BPCI model design features was released over 4 years ago, in August 2011. We now have two years of experience with BPCI Model 2 Awardees, the model that most closely resembles the CJR model, in the risk-bearing period, and the year 1 BPCI annual evaluation and monitoring report from February 2015 is publicly available on the CMS Web site at: *https://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf*. We have developed and adopted a variety of new quality measures in programs and models since 2011, as well as gained experience with pay-for-reporting and pay-for-performance in a variety of models and programs involving a wide range of health care providers and clinical conditions. Given our extensive experience over the past several years with pay-for-performance approaches, the availability of existing measures that reflect the quality of care for elective THA/TKA episodes, and the breadth of the CJR model, which reaches

substantially all IPPS hospitals in the selected MSAs, including those hospitals who otherwise would not participate in a voluntary payment model, we believe that a pay-for performance approach is necessary and appropriate beginning in the model's first performance year. IPPS hospitals have substantial experience over multiple years with CMS programs that include pay-for-performance and we believe, given the proposed quality measures for the CJR model, that CJR pay-for-performance in an episode payment model is a natural extension to bundled payment of pay-for-performance measures used in current CMS programs. While we acknowledge that pay-for-performance is not the only way for a model to heighten a focus on maintaining or improving the quality of LEJR episode care, we believe that the CJR model, like other Innovation Center models, should target both improved quality and reduced costs. Based on our experience in other programs and models, we believe that pay-for-performance under the CJR model shows great promise in moving participant hospitals toward greater efficiency and higher quality of LEJR episodes. In view of successful implementation of pay-for-performance in other CMS hospital programs using similar quality measures that has resulted in significant improvements in the quality of care, we believe IPPS hospitals have sufficient experience to be ready for pay-for-performance under the CJR model. We expect that other features of the model design, including our plans for data sharing, will help participant hospitals committed to care redesign toward these goals achieve success on both quality and cost performance for episodes.

We note that the quality measures finalized for the model as discussed in section III.D.2. of this final rule rely upon data that hospitals are already submitting and which are already analyzed by CMS for other programs, so we see no reason to adopt a period of pay-for-reporting for the first performance year of the model or longer. In the proposed rule, we considered a similar policy that would not penalize hospitals with regard to their eligibility for reconciliation payments for failure to meet the proposed quality measure thresholds in performance year 1. However, we continue to believe that adopting pay-for-reporting and not pay-for-performance in performance year 1 or longer would be inappropriate given that two of the proposed quality measures are administrative claims-based measures and impose no additional reporting burden on hospitals, the proposed measures are all established measures in existing CMS quality programs, and a central goal of the CJR model is improving care for Medicare beneficiaries in LEJR episodes. In this regard, the CJR model is different from some other CMS value-based initiatives where the data for some measures were newly submitted by providers or newly analyzed by CMS early in the initiative. Furthermore, we do not believe that participant hospitals need a year of pay-for-reporting to develop systems for analyzing episode claims under the model, as we expect hospitals to already be focused on improving their performance on these measures. The two measures finalized for the CJR model are aligned with the goals of the CJR model, are familiar to hospitals based on their use in other CMS hospital programs, and are aligned with CMS priorities to reduce LEJR complications while improving the patient experience. Because the measures reflect these goals and accurately measure hospitals' level of achievement and improvement on quality outcomes that are important to beneficiaries undergoing LEJR procedures, we are finalizing our proposal to implement a pay-for-performance approach in the CJR model in the first performance year by using quality performance in the episode payment methodology.

*Comment:* Some commenters supported the proposed strategy to link quality to payment through performance thresholds for quality measures that would result in reconciliation payment eligibility if the thresholds were met. Several commenters further reasoned that there should be no need to increase thresholds for reconciliation payment eligibility over the performance years of the model as CMS had proposed because the possibility of reconciliation payment provides an adequate quality improvement incentive. A commenter in favor of the proposed threshold approach recommended that CMS make the proposed THA/TKA voluntary patient-reported outcome (PRO) data submission mandatory and significantly increase incentives around their collection.

A number of commenters estimated that under CMS' proposal, more than half of the participant hospitals would be ineligible for reconciliation payments based on their current quality measure performance, even if episode savings were achieved during a performance year. The commenters stated that CMS should not use performance percentiles that would always exclude a predetermined number of participant hospitals from reconciliation payments, and hold hospitals to multiple quality performance standards for the same measure performance under different CMS models and programs. They contended that performance percentiles, as measures of relative performance, do not reflect best practices and, therefore, recommended that CMS require a level of absolute measure performance rather than relative performance when incorporating quality performance into the payment methodology under the CJR model. The commenters did not describe the absolute levels of performance that they would recommend on the quality measures for the CJR model. Several commenters claimed that the use of thresholds for reconciliation eligibility disadvantages small hospitals because only one or two patient instances could change the participant hospital's performance percentile and, therefore, affect the hospital's eligibility for reconciliation payments. Other commenters pointed out that the Shared Savings Program uses quality thresholds, but the methodology accounts for improvement and the program is voluntary, while hospital participation would be required in the CJR model and improvement was not considered in the pay-for-performance methodology CMS proposed.

Other commenters asserted that CMS' proposal linking quality measure performance to eligibility for reconciliation payments failed to reflect the quality of care delivered in the context of the model due to flaws in the proposed approach to determining participant hospital performance in relation to the thresholds. The commenters contended that the proposed methodology to determine performance on quality measures and link performance to reconciliation payment eligibility uses arbitrary distinctions in performance among hospitals that are not borne out by the data or even by CMS's own method of assigning ratings of performance on the *Hospital Compare* Web site. They stated that use of measure result point estimates to determine performance percentiles under CMS' proposal for performance thresholds for reconciliation payment eligibility may not be appropriate because: (1) The THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) are a ratio comparing observed to expected outcome, where expected is based on the national performance, so an individual hospital's performance

should be assessed within confidence intervals as the measure was originally specified, tested, and endorsed by the NQF; and (2) there may not be a clinically and statistically significant difference in the performance of hospitals immediately above and below the 30th percentile. The commenters observed that while the HRRP uses measure result point estimates (the same measure results proposed in section III.C.5.b.(5)(b) of the proposed rule, which proposed to use the absolute values of the CJR model participant hospital measure results) in calculating the excess readmission ratio in accordance with the statutory provision that defines this ratio, they stated that CMS has the flexibility under the statutory authority for the CJR model to use confidence intervals in determining outcome measure results for use in the payment methodology.

A number of commenters recommended that CMS adopt a threshold methodology that would utilize the confidence intervals used on the *Hospital Compare* Web site that distinguishes performance based on the three categories of comparison to the national rate on the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) to determine if a participant hospital is eligible for reconciliation payment. On *Hospital Compare,* hospitals are grouped into ''no different than national rate,'' ''better than national rate,'' or ''worse than national rate'' for each measure. The commenters recommending this methodology recommended against use of the HCAHPS Survey measure (NQF #0166).

Therefore, the commenters maintained that CMS should modify its proposal and set the quality performance thresholds for reconciliation payment eligibility at ''worse than national rate,'' rather than at the 30th percentile or above compared to the national rate. Specifically, the commenters suggested if performance on both the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) is statistically ''worse than national rate,'' then a participant hospital should not be eligible for reconciliation payment. Those hospitals that are deemed ''no different than national rate'' or ''better than national rate'' on both measures should automatically be deemed eligible for any potential reconciliation payment. Some commenters further urged CMS to also allow participant hospitals performing ''worse than national rate'' on one or both quality measures to receive reconciliation payments if CJR model episode savings were achieved as long as the hospital submits a corrective action plan to CMS describing their future strategies to improve quality of care, including contributing a portion of the reconciliation payment to quality performance improvement strategies. These commenters asserted that the quality performance thresholds should provide equal financial opportunity and incentives to all hospital participants.

The commenters claimed that setting quality performance thresholds at the level of ''worse than national rate'' as displayed on the *Hospital Compare* Web site would reduce confusion among the public with an interest in hospital performance under the CJR model, and strike an appropriate balance between encouraging hospital to focus on quality performance and providing hospitals with a fair opportunity to receive reconciliation payments if episode savings are achieved. A commenter reported that nationally there are 22 hospitals with performance on the THA/TKA Complications measure (NQF #1550) or the THA/TKA Readmissions measure (NQF #1551) that is ''worse than national rate,'' and only one hospital that is ''worse than national rate'' on both measures.

*Response:* We appreciate the support of some commenters for our proposal to set performance thresholds for reconciliation payment eligibility at the 30th percentile based on the national distribution of measure results, as well as the concerns expressed by some commenters about using relative performance to assess participant hospital episode quality performance in the CJR model. We continue to believe that relative measure performance is the most appropriate way to incorporate quality performance into the CJR model because we do not have sufficient information about hospital performance to set and use an absolute performance result on each measure. We believe that hospitals nationally are working to improve their performance on the quality measures proposed for the CJR model on an ongoing basis and, thus, while we expect that CJR participant hospitals will have a heightened focus on improvement on these measures as a result of the financial incentives resulting from episode payment, we are not yet certain in this model test what performance outcomes can be achieved under best practices. Therefore, we will not set absolute performance results as quality thresholds for reconciliation payment eligibility under the CJR model. We continue to believe that relative measures of quality performance are most appropriate for the CJR model as hospitals continue to make progress nationally on improving patient outcomes.

Furthermore, we will not make THA/TKA voluntary PRO and limited risk variable data submission mandatory and increase the incentives around their collection in the CJR pay-for-performance methodology as recommended by a commenter. This measure remains under development, and we want to encourage robust hospital reporting to speed measure development, but the measure is not yet ready to have its results incorporated in the CJR model methodology in the manner recommended by the commenter. We refer readers to section III.D.3.a. of this final rule for further discussion of our future plans to incorporate PRO measure results in the CJR pay-for-performance methodology.

We appreciate the suggestions of many commenters that we utilize outcome measure thresholds of ''worse than national rate'' as displayed on the Hospital Compare Web site to set the thresholds for reconciliation payment eligibility. For purposes of the *Hospital Compare* Web site, we made a specific choice around categorizing hospitals to performance categories for public display of hospital measure results in order to display a high level of statistical certainty about differences in hospital quality performance that would be reviewed by beneficiaries and other members of the public. Specifically for the *Hospital Compare* Web site, to assign hospitals to performance categories, the hospital's interval measure estimate is compared to the national rate. If the 95 percent interval estimate includes the national observed rate for that measure, the hospital's performance is in the ''no different than national rate'' category. If the entire 95 percent interval estimate is below the national observed rate for that measure, then the hospital is performing ''better than national rate.'' Finally, if the entire 95 percent interval estimate for the hospital is above the national observed rate for that measure, the hospital's performance is ''worse than national rate.''

Regarding the commenter who suggested that an individual hospital's performance on a measure should be assessed within confidence intervals as the measure was originally specified, tested, and endorsed by the NQF, we note that the THA/TKA Complications measure (NQF #1550) was not endorsed by the National Quality Forum for its use with an interval estimate, since NQF endorses measure specifications and not the use of measures in various programs

or models. We acknowledge that CMS uses outcome measure ratios and rates in different ways that may lead to some confusion for stakeholders. We also want to clarify that during measure development of the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551), these measures were developed and tested to yield risk-standardized ratios, which are multiplied by the national rate and reported as risk-standardized rates in *Hospital Compare*, and that the 95 percent interval estimate is specifically used to display the measure for public reporting on the *Hospital Compare* Web site. We chose to use rates on the *Hospital Compare* Web site because we believe that presentation of a rate on the *Hospital Compare* Web site is better understood by consumers than a measure result expressed as a predicted-to-expected ratio. For purposes of the CJR model, we will also use risk-standardized rates for the THA/TKA Complications measure (NQF #1550) as discussed in section III.D.2.a. of this final rule. We discuss our final decision not to adopt the THA/TKA Readmissions measure (NQF #1551) for this model in section III.D.2.b. of this final rule.

We note that ''worse than national rate'' is the quality performance threshold for reconciliation payment eligibility recommended by many commenters as the statistically certain measure of poor hospital quality performance, yet almost every hospital in the country already exceeds this level on the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). Nationally, we estimate that only 29 hospitals currently perform at ''worse than national rate'' on one or more of these measures, a number that is similar to the estimate provided by a commenter. Thus, based on current measure performance only a very small number of hospitals would fail to meet the quality performance thresholds for reconciliation payment eligibility recommended by many commenters. We do not believe that adopting ''worse than national rate'' as the threshold for reconciliation payment eligibility, or applying no threshold as recommended by some commenters if a hospital ''worse than national rate'' submits a corrective action plan to CMS, would further encourage quality improvement or maintenance of high performance for participant hospitals in the CJR model, beyond the incentives that already exist in CMS programs.

Either incorporating a ''worse than national rate'' threshold or applying no threshold would essentially eliminate pay-for-performance under the CJR model, which would not be consistent with our final decision discussed in the prior response to public comments to incorporate a pay-for-performance methodology in the CJR model beginning in performance year 1.

Regarding the recommendations to use interval estimates to identify hospitals with performance ''worse than national average'' as the most equitable approach to identifying statistically valid poor hospital performance on quality measures, we have previously explained our position on the use of interval estimates when determining payment outcomes for hospital performance on measures. Specifically for the HRRP where we use point estimates for quality measure performance, we acknowledged outcome measures of risk-standardized condition-specific readmission rates to be statistical measures (77 FR 53394). We also recognized that statistical measures will include some degree of variation and stated that other Medicare programs use similar statistical measures as part of their programs, so any consideration of the use of interval estimates with respect to the HRRP may have implications for other programs (77 FR 53394). Despite this reality, we finalized the HRRP methodology for quality measure performance (76 FR 51673), which results in the use of a point estimate for a hospital's excess readmission ratio (77 FR 53394), and we use point estimates in other CMS programs that rely upon statistically-based outcome measures, such as the HVBP Program. (76 FR 26504). We note that over the past several years the HRRP has shown that use of point estimates in the program has still led to improvement in hospital readmission rates.[42] [43] We, therefore, continue to believe that quality performance can be assessed by measure result point estimates that do not rely on the statistical certainty of interval estimates which may fail to identify real, clinically meaningful differences in hospital measure performance.

However, we agree with the commenters that our proposal to set performance thresholds for reconciliation payment eligibility at the 30th percentile does not reflect the statistical certainty of intervals around hospital measures performance results and may not adequately account for the variation that occurs in risk-standardized rates like the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) proposed for use in the CJR model. We also agree with the commenters that setting required measure performance thresholds for reconciliation eligibility may provide insufficient quality and cost episode improvement incentives for some participant hospitals in the CJR model. We estimate that based on their current quality measure performance one-third of participant hospitals would not be eligible for reconciliation payments under our proposed thresholds for the three required quality measures, even if those hospitals achieved savings beyond the target price. While our estimate is lower than the estimate of more than 50 percent of participant hospitals that was provided by some commenters, we agree with the commenters that the proposed methodology would not provide significant quality and cost episode improvement incentives for a substantial percentage of participant hospitals in the CJR model.

We continue to believe there are real, clinically meaningful differences that are important to Medicare beneficiaries in hospital performance on the THA/TKA Complications measure (NQF #1550) finalized for this model, as well as opportunities for improvement, which are not recognized by the statistical certainty approach that we use for the *Hospital Compare* Web site but can be appropriately recognized by assigning hospitals to measure performance percentiles, such as we proposed for the CJR model. We also believe it is appropriate to make different choices for estimating measure performance for model or program payment policies, depending on the context. For example, in the CJR model where we proposed to use quality performance in the payment methodology of a model specifically focused on quality outcomes directly addressed by the proposed measures, we believe a different approach to estimating performance differences than the statistical certainty approach used on the *Hospital Compare* Web site would allow us to observe and reward real quality performance incentivized by episode payment that otherwise would

[42] Gerhardt G, Yemane A, Hickman P, Oelschlaeger A, Rollins E, Brennan N. Data Shows Reduction in Medicare Hospital Readmission Rates During 2012. Medicare & Medicaid Research Review 2013: 3(2): E1–E12.

[43] Medicare Hospital Quality Chartbook 2014: Performance Report on Outcome Measures. Prepared by Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation for the Centers for Medicare and Medicaid Services 2014:23. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf.*

be unrecognized. Therefore, we continue to believe that assigning hospital measure results to a performance percentile in comparison with the national distribution is an appropriate strategy to categorize and recognize hospitals achieving different levels of quality performance on the measures. We note that assigning hospitals to performance percentiles based on their measure result point estimates, and then using deciles of performance in a pay-for-performance model payment methodology that does not use hospital performance percentiles as thresholds, would help account for some of the statistical variation that could occur in measure result point estimates and reduce the likelihood that we would consider variation to be a real change in measure performance. Therefore, we are finalizing our proposal discussed in section III.C.5.b.(5)(b) of this final rule to assign each participant hospital's measure point estimate to a performance percentile based on the national distribution of measure results. However, because the statistical uncertainty in measure results increases the challenge of determining the most equitable performance threshold, below which the level of performance is no longer in the best interest of the beneficiary, as well as our interest in providing quality and cost episode improvement incentives for all participant hospitals under the CJR model, we are not finalizing our proposal to set performance percentile thresholds for reconciliation payment eligibility in the CJR model. Because we are not using performance percentile thresholds for reconciliation payment eligibility in the CJR model's final pay-for-performance methodology, we will neither be setting nor changing such thresholds in the context of the model's payment methodology over the model's performance years. We will be adopting the composite score methodology, as discussed in the following response to comments.

*Comment:* Many commenters offered a variety of other perspectives on CMS' proposal and alternatives considered to link quality and payment in the CJR model. Several commenters recommended that CMS tie a portion of the reconciliation payment to the proposed quality measure threshold performance for each of the 3 measures, specifically: ⅓ of the reconciliation payment would be made if one of the quality measure performance thresholds is achieved, ⅔ of the reconciliation payment would be made if two of the quality measure performance thresholds were achieved, and the full reconciliation payment would be made if all three quality measure performance thresholds were achieved. These commenters urged CMS to accompany this policy with no repayment responsibility in all years for participant hospitals that achieved all three quality measure performance thresholds, even if actual episode spending exceeds the target price. The commenters reasoned that this revised approach would provide the potential for more financial reward for participant hospitals providing high quality episode care, and limit the financial risk for participant hospitals furnishing high quality care.

Some commenters who opposed the use of performance percentiles on quality measures that were included in CMS' threshold proposal also opposed the alternative composite quality score approach for the same reasons, mainly because it would rely on performance percentiles derived from point estimates of quality measure performance to award points toward the composite quality score. However, a number of commenters favored the use of a composite quality score to link quality and payment, rather than thresholds for reconciliation payment eligibility, because the composite quality score would provide an opportunity for more participant hospitals to receive reconciliation payments if episode savings were achieved and would vary a participant hospital's financial reward in direct relationship to its episode quality performance.

Other commenters suggested further refinements to the composite score methodology, including different weighting of the measures. A commenter urged CMS to reconsider the composite score weights discussed in the proposed rule, and establish them as: HCAHPS Survey 25 percent; Complications 50 percent, and Readmissions 25 percent. The commenter reasoned that the Readmissions measure weight should be reduced due to the measure's use in other CMS programs. Finally, the commenter recommended that CMS modify the minimum percentile to receive quality measure score points to the 10th percentile, and add a band for incremental performance between the 10th percentile and the current national average performance, where an increasing proportion of any reconciliation payment from episode savings would be paid. The commenter urged CMS to pay the full reconciliation payment for episode savings beyond the target price to any hospital with quality performance above the national average.

Several commenters, who also recommended additional quality measures, stated that CMS should place greater weight in the composite quality score on ambulation, followed by pain experience and management, and finally followed by the Complications, Readmissions, and HCAHPS Survey measures in descending order of importance when calculating the composite quality score. Another commenter contended that CMS should increase the HCAHPS Survey measure weight and make the submission of THA/TKA voluntary PRO and limited risk variable data mandatory for performance year 2 and subsequent years, to increase the effect of patient experience on the financial opportunity of participant hospitals under the CJR model. A commenter recommended that, rather than participant hospital percentiles of performance compared to the national distribution of hospital measure performance, CMS use hospital-specific metrics that should be able to ''top out'' with high quality performance. The commenter suggested that CMS could measure performance annually on each measure for every participant hospital, and establish a minimum and maximal optimal measure result for the measure that could guide performance scoring. Finally, a commenter urged CMS to reconsider awarding the 50th percentile of performance for individual measure scores that make up the composite quality score without actual measure results, as CMS would not be assured that those hospitals were providing good quality care.

A number of commenters recommended that CMS vary the discount percentage incorporated in the target price at reconciliation based on the participant hospital's level of quality performance. Other commenters stated that high-performing hospitals on quality should have opportunities for greater reconciliation payments if that high-quality performance is sustained, recommending that CMS include no discount in the target price or a smaller discount percentage for these hospitals than would be used for hospitals with lower levels of quality performance. Finally, several commenters contended that hospitals furnishing care of lower quality should incur financial penalties based on their quality performance.

*Response:* We appreciate the suggestions of the commenters on features of the CJR pay-for-performance methodology that would be valuable in providing the most robust incentives for quality improvement or maintenance of high-quality performance for all CJR participant hospitals. As described

previously in this section, we are finalizing our proposal discussed in section III.C.5.b.(5)(b) of this final rule to assign each participant hospital's quality measure result point estimate to a performance percentile based on the national distribution of measure results, but we are not finalizing our proposal to set performance percentile thresholds for reconciliation payment eligibility under the CJR model.

We agree with many of the commenters that the pay-for-performance methodology under the CJR model should provide the opportunity for financial reward to participant hospitals with an acceptable level of episode quality performance, while also including an incentive for quality improvement if the hospital's current level of quality is low. We also agree with the commenters who stated that the CJR pay-for-performance methodology should provide the potential for increased financial reward for participant hospitals that furnish higher-quality care through payments that would either increase the reconciliation payment to the hospital or reduce the hospital's repayment responsibility depending on the hospital's episode cost performance for the model performance year. However, we do not agree with the commenters who recommended that those hospitals achieving high-quality episode performance should not be expected to improve their episode efficiency because we believe that substantial opportunities to reduce Medicare expenditures in the context of high-quality episode care exist for virtually all participant hospitals. Innovation Center models are generally designed with a focus on both reducing costs and improving the quality of care for model beneficiaries. Therefore, we will continue to incorporate a discount percentage into the target price for every participant hospital as discussed in section III.C.4.b. of this final rule in the methodology for setting target prices for the CJR model.

We also do not agree with the commenters who recommended that hospitals with low-quality performance incur financial penalties under the model, because the model is specifically designed to reward episode quality performance and cost savings. We discussed an alternative under the composite quality score approach in section III.C.5.b.(5)(c)(ii) of the proposed rule that would impose a quality penalty on hospitals with a low composite quality score that would otherwise lead them to be ineligible for reconciliation payments (80 FR 41243 through 41244). Under this alternative, we would reduce the effective discount percentage for these hospitals, thus imposing a 1 percent penalty for their low quality performance, regardless of whether or not episode savings are achieved beyond the target price. We continue to believe that while this approach would provide stronger incentives for quality improvement for participant hospitals with low performance on quality, even if they did not expect to be able to reduce actual episode spending below the target price, it could provide reconciliation payments even to those hospitals that did not achieve acceptable quality performance. Therefore, we believe that the risk to beneficiaries and CMS of these low-quality performing hospitals achieving savings in the context of poor quality care by sharply decreasing utilization to levels that reflect stinting on medically necessary care are so significant that adopting this alternative would not be appropriate. Instead, we will provide the opportunity for quality incentive payments that relate to the participant hospital's overall quality performance and improvement on the model's quality measures as reflected in the hospital's composite quality score that we will calculate for each performance year at the time reconciliation is carried out for that performance year.

As previously discussed, we are not finalizing our proposal to set performance percentile thresholds for reconciliation payment eligibility in the CJR model. Based on public comments that addressed our reconciliation payment eligibility threshold proposal, the alternatives considered, and the objectives of the pay-for-performance methodology under the CJR model, we believe that the composite score methodology that we discussed in the proposed rule that would determine reconciliation payment eligibility and change the effective discount percentage experienced by a participant hospital at reconciliation is the most appropriate pay-for-performance approach to achieve the objectives previously described. While the majority of commenters favored the threshold proposal with modification to adopt much lower quality thresholds of ''worse than national average'' performance that would result in eligibility of almost all participant hospitals for reconciliation payments if savings were achieved beyond the target price, a substantial percentage of commenters supported the composite score methodology or another approach that would provide greater financial reward to participant hospitals for higher quality performance. The composite score methodology omits the proposed 30th percentile performance minimum standard for all required quality measures as a definitive cut-off point for eligibility for reconciliation payments and replaces it with a quality scoring system that provides hospitals with multiple possible combinations of quality performance that can result in a hospital reaching eligibility for the reconciliation payment, thereby providing opportunity for reconciliation payments to hospitals achieving an acceptable or higher level of overall quality performance. This methodology also provides an incentive structure that acknowledges that high-quality episodes should be rewarded with greater financial opportunity under the CJR model, either through increased reconciliation payments or reduced repayment responsibility, depending upon the participant hospital's episode cost performance during a performance year. We appreciate the support of the commenters who share our view on the merits of the composite score approach.

We discussed in the proposed rule, but did not propose, a composite quality score methodology because at the time we believed that such an approach could diminish the importance of each quality measure given the limited number in the model, that the measures represented clinical goals that should be achievable by all hospitals participating in the model, and that a threshold methodology would provide the most achievable and predictable quality targets for the CJR model that requires participation (80 FR 41244). However, we agree with the commenters that the proposed threshold methodology would not sufficiently incentivize and reward quality improvement and acceptable or high quality performance under the CJR model for a substantial proportion of participant hospitals even if savings beyond the target are achieved. In contrast, the composite quality score methodology will allow performance on each required quality measure to be meaningfully valued in the model's pay-for-performance methodology, incentivizing and rewarding cost savings in relation to the quality of episode care provided by the participant hospital. Despite the small number of final CJR model quality measures, the measures represent both clinical outcomes and patient experience, and each carries substantial value in the composite quality score. Participant hospitals could achieve an acceptable or good composite quality score despite performing well on one of the required measures but achieving lower

performance on the other required measure. Thus, while quality performance on each measure would not be required for reconciliation payment eligibility, performance on each measure would be valued in the composite quality score methodology. Based on our review of the public comments, including the technical issues raised about measure result statistical variation in point estimates, we believe that a participant hospital's overall quality performance under the CJR model should be considered in the pay-for-performance approach, rather than performance on each quality measure individually determining the financial opportunity under the model. The composite score methodology also provides a framework for incorporating additional measures of meaningful outcomes for LEJR episodes, as discussed in section III.D.3. of this final rule, in the CJR pay-for-performance methodology in the future. Finally, while we believe that high quality performance on all of the measures represents goals of clinical care that should be achievable by all CJR model participant hospitals that heighten their focus on these measures, we appreciate that many hospitals have room for significant improvement in their current measure performance. The composite score methodology, which does not set performance thresholds for each measure for reconciliation payment eligibility, will provide the potential for financial reward for more participant hospitals that reach overall acceptable or better quality performance, thus incentivizing their continued efforts to improve the quality and efficiency of episodes.

In the proposed rule, we presented weights for the proposed quality measures in the composite quality score and note that we need to revise those weights for the final rule given that we are not adopting the THA/TKA Readmissions measure (NQF #1551) for the CJR model. As some commenters encouraged us to assign more weight than we discussed in the proposed rule to measures of patient experience and functional status, we believe it would be most appropriate to redistribute the 20 percent measure weight from the THA/TKA Readmissions measure (NQF #1551) equally to the two required measures we adopted for the model, specifically assigning an additional 10 percent weight each to the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166). We note that the overall distribution of measure weight in the composite quality score would provide 50 percent weight to health-related conditions that arise following LEJR surgery (through the THA/TKA Complications measure (NQF #1550)) and 50 percent weight to patient experience (through the HCAHPS Survey measure (NQF #0166) and THA/TKA voluntary PRO and limited risk variable data submission). We believe this weighting appropriately balances patient experience with meaningful health outcomes for beneficiaries, by providing equal weight in the composite quality score to both dimensions, consistent with the patient-centered priorities for quality measurement that some commenters urged us to adopt.

The final measure weights in the composite quality score for the CJR model are displayed in Table 17.

TABLE 17—FINAL QUALITY MEASURE WEIGHTS IN COMPOSITE QUALITY SCORE

| Quality measure | Weight in composite quality score (%) |
|---|---|
| Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550) | 50 |
| HCAHPS Survey (NQF #0166) | 40 |
| THA/TKA voluntary PRO and limited risk variable data submission | 10 |

Consistent with the scoring of individual measure percentile performance as assigned to a decile, as we discussed in the proposed rule, and our final decision to use performance percentiles for both required quality measures, as discussed earlier in this section, for each model performance year we will assign individual measure performance scores to each participant hospital based on the values in Table 18. These individual measure performance scores have been set to reflect the final measures weights in Table 17 so they can ultimately be summed without adjustment in calculating the composite quality score. The absolute differences for each performance decile among the two measures reflect the intended weight of the measure performance in the composite quality score.

As we further discussed in the proposed rule, we will assign participant hospitals without a measure value to the 50th performance percentile (80 FR 41242). A participant hospital will not have a value for the THA/TKA Complications measure (NQF #1550) if the hospital does not meet the minimum case count of 25 cases in the 3 year measurement period which is required to ensure reliability of the measure result. In section III.D.4. of this final rule, we discuss the 25 case minimum and note that this quality measure case minimum is the same as the minimum used in the HIQR Program (75 FR 50185 and 76 FR 51609). We further note that as described in section III.D.2.a. of this final rule, the THA/TKA Complications measure (NQF #1550) only includes primary elective THA/TKA procedures which are a subset of the LEJR episodes included in the CJR model. As a result, it is possible for a CJR participant hospital to have LEJR episodes but no cases that meet the criteria to be included in the THA/TKA Complications measure (NQF #1550). Regarding the HCAHPS Survey measure (NQF #0166), a participant hospital will not have a reported value for the HCAHPS Survey measure (NQF #0166) if it did not meet the minimum of 100 completed surveys and did not have 4 consecutive quarters of HCAHPS data, which are required to ensure the reliably of the measure. In section III.D.4. of this final rule, we discuss the 100 case minimum and note that this quality measure case minimum is the same as the minimum used in the HVBP Program (76 FR 26502).

Moreover, we note that in rare cases, if CMS identifies an error in the data used to calculate the measure resulting in suppression of the data for public reporting on *Hospital Compare,* a hospital will not have a value for the THA/TKA Complications measure (NQF #1550) or HCAHPS Survey measure (NQF #0166) measure and would be assigned to the 50th performance percentile of the measure, as applicable.

Lastly, new hospitals that are identified as participants in the CJR model may not have sufficient data within the measure performance periods to calculate a value for the THA/TKA Complications measure (NQF #1550) or HCAHPS Survey measure (NQF #0166) and would be assigned to the 50th performance percentile of the measure, as applicable.

For hospitals that are in the situations previously described, we will assign participant hospitals without a measure value the 50th performance percentile of the measure result distribution. We intend to publicly report the measure results used to calculate the composite quality score for all participant hospitals. While we understand the concerns of the commenter that we have no actual outcome measure results for certain hospitals, we continue to believe it would be unfair to disadvantage a participant hospital in the pay-for-

performance methodology of this model based on insufficient number or no applicable cases alone and, therefore, we will assign these hospitals to the 50th performance percentile, which is the middle of the national measure performance distribution, and assign quality performance points to the participant hospital accordingly based on the performance percentile scale identified in Table 18.

Moreover, as we also discussed in the proposed rule, we will not assign individual measure score performance points to a hospital categorized to a performance percentile below the 30th percentile because we do not believe lower performance percentiles reflect quality performance such that they should be assigned any individual quality measure score performance points for LEJR episodes under the CJR model. Although a commenter suggested providing individual quality measure score points to hospitals beginning at the 10th performance percentile, we continue to disagree that performance below the 30th performance percentile reflects sufficient quality on these two well-established measures in CMS hospital programs to award quality measure points. We note, however, that a participant hospital assigned no performance points for one required quality measure could still be eligible for reconciliation payments if episode savings are achieved beyond the target price as long that hospital has achieved a sufficient performance percentile on the other required quality measure.

Additionally, we will assign a measure quality score of two points for participant hospitals that successfully submit THA/TKA voluntary PRO and limited risk variable data and 0 points for participant hospitals that do not successfully submit these data. The requirements for successful data submission in each performance year are discussed in section III.D.3.a. of this final rule. While we discussed awarding 1 point for successful submission in the proposed rule, this was an error because we also stated that the submission of THA/TKA voluntary PRO and limited risk variable data would constitute 10 percent of the composite quality score, which is based on a maximum score of 20 points. Two points is the correct value that reflects 10 percent of the maximum score.

TABLE 18—FINAL INDIVIDUAL SCORING FOR TWO REQUIRED QUALITY MEASURES

| Performance percentile | THA/TKA Complications measure (NQF #1550) quality performance score (points) (1 additional point available for improvement) | HCAHPS Survey measure (NQF #0166) quality performance score (Points) (0.8 additional point available for improvement) |
|---|---|---|
| ≥90th | 10.00 | 8.00 |
| ≥80th and <90th | 9.25 | 7.40 |
| ≥70th and <80th | 8.50 | 6.80 |
| ≥60th and <70th | 7.75 | 6.20 |
| ≥50th and <60th | 7.00 | 5.60 |
| ≥40th and <50th | 6.25 | 5.00 |
| ≥30th and <40th | 5.50 | 4.40 |
| <30th | 0.00 | 0.00 |

We will sum the performance and, if applicable, improvement scores (as discussed in the following response to comments) on the two required quality measures with the score on the successful submission of THA/TKA voluntary PRO and limited risk variable data to calculate a composite quality score for each performance year for a participant hospital. This composite quality score will then be incorporated into the pay-for-performance methodology for the CJR model that assigns a participant hospital to a quality category at the time of reconciliation for a performance year. We will first require a minimum composite quality score for reconciliation payment eligibility if the participant hospital's actual episode spending is less than the target price and second, make quality incentive payments that change the effective discount percentage included in the target price experienced by the hospital in the reconciliation process. Thus, hospitals with higher composite quality scores may financially benefit from their episode quality performance compared to hospitals with lower quality performance in a different quality category, regardless of whether episode savings are achieved. For example, in performance year 4, actual episode spending for a hospital with an excellent composite quality score would be reconciled to a target price reflecting a 3.0 percent discount factor, but then the participant hospital would receive a quality incentive payment of 1.5 percent of the hospital's pre-discount target price that would either increase the hospital's reconciliation payment if savings were achieved or reduce the hospital's repayment responsibility if actual episode spending exceeded the target price. In contrast, actual episode spending for a hospital with an acceptable composite quality score would be reconciled to a target price reflecting a 3.0 percent discount factor, but then the participant hospital would not receive any quality incentive payment. Thus, the excellent quality performance by the participant hospital in the excellent quality category would provide a financial benefit to that hospital of 1.5 percent of the pre-discount target price, regardless of whether the hospital achieved savings for episodes.

As discussed in the proposed rule regarding the composite quality score alternative approach to pay-for-for performance under the CJR model, the discount for all participant hospitals included in the target prices will be 3.0 percent. We refer readers to section III.C.4.b.(9) of this final rule for further discussion of the discount factor included in the target prices. Hospitals that provide high-quality episode care will have the opportunity to receive quality incentive payments that will reduce the effective discount percentage as displayed in Tables 19, 20, and 21, based on their composite quality score that places each hospital into one of four quality categories, specifically ''Below Acceptable,'' ''Acceptable,'' ''Good,'' and ''Excellent.'' Three tables are required to display the effective discount percentages for each quality category due to the phase-in of hospital repayment responsibility from no responsibility in performance year 1, to partial responsibility in performance

years 2 and 3, and finally full responsibility in performance years 4 and 5 as discussed in section III.C.4.b.(9) of this final rule. Depending on the participant hospital's actual composite quality score that places the hospital in a quality category, quality incentive payments will be valued at 1.0 percent to 1.5 percent of the hospital's benchmark episode price (that is, of the expected episode spending prior to application of the discount factor to calculate a target price).

While the final policy to place participant hospitals into one of four quality categories to determine reconciliation payment eligibility and, if applicable, the value of quality incentive payments is the same as that presented in the proposed rule, the applicable scoring ranges for each quality category discussed in the proposed rule are different from the ranges we are finalizing in Tables 19, 20, and 21 for several reasons. First, we are not finalizing the THA/TKA Readmissions measure (NQF #1551) as part of the CJR model's pay-for-performance methodology, requiring us to redistribute the 20 percent weight in the composite quality score that we had presented for that measure. That redistribution is discussed earlier in this section. Second, our final policy includes quality improvement points in addition to quality performance points in the composite quality score, as discussed in the following response to comments. We estimate based on current quality measure performance that approximately 4 percent and 7 percent of all participant hospitals would qualify for improvement points on the HCAHPS Survey measure (NQF #0166) and the THA/TKA Complications measure (NQF #1550), respectively.

The most significant reason for a change in the scoring ranges for the quality categories in the final rule is due to our strengthening the financial incentives for participant hospitals under the CJR model through the composite quality score pay-for-performance methodology to improve quality performance or maintain high-quality performance for episodes. We agree with the commenters who urged us to ensure that most participant hospitals that achieve savings beyond the discount included in the target price receive reconciliation payments if their episode quality is acceptable and that we provide the potential for significantly greater financial reward for hospitals that achieve or maintain high quality episode performance. Therefore, we have reassessed our quality performance expectations for each quality category by examining the current quality measure performance of participant hospitals in the context of the national measure performance distribution. We have adjusted the final scoring ranges to balance the quality performance required for each quality category with the financial incentives (reconciliation payment eligibility and quality incentive payments) to achieve the quality performance required for the category. In the context of our final composite quality score ranges for each quality category, we estimate that approximately 10 percent of participant hospitals placed in the ''Below Acceptable'' quality category based on their composite quality score would not be eligible for reconciliation payments based on their current quality measure performance, compared to 14 percent based on the proposed rule composite score measures and ranges. Similarly, we estimate that approximately 12 percent of participant hospitals would be eligible for reconciliation payments through placement in the ''Acceptable'' quality category but would not receive quality incentive payments based on their current quality performance, compared to 30 percent in this quality category based on the proposed rule measures and score ranges. We estimate that the large majority of participant hospitals, specifically 64 percent, would be placed in the ''Good'' quality category based on their current quality performance and would, therefore, be eligible for reconciliation payments and for quality incentive payments valued at 1.0 percent of the hospital's benchmark episode price, compared to 46 percent based on the proposed rule measures and score ranges. Finally, we estimate that 14 percent of participant hospitals through placement in the ''Excellent'' quality category would be eligible for reconciliation payments and for quality incentive payments valued at 1.5 percent of the hospital's benchmark episode price, compared to an estimate of 10 percent based on the proposed rule measures and score ranges. Thus, for each quality performance category, we have slightly lowered our quality performance expectations from our proposed rule discussion of the composite quality score approach, in order to provide participant hospitals with more significant financial incentives to improve their quality and cost performance under the CJR model, as well as their incentives to maintain high-quality performance.

Hospitals will be required to achieve a minimum composite quality of score greater than or equal to 4.0 to be eligible for a reconciliation payment if actual episode spending is less than the target price. Participant hospitals with below acceptable quality performance reflected in a composite quality score less than 4.0 will be assigned to the ''Below Acceptable'' quality category and will not be eligible for a reconciliation payment if actual episode spending is less than the target price. A level of quality performance that is below acceptable will not affect participant hospitals' repayment responsibility if actual spending exceeds the target price. We believe that the requirement that this minimum level of LEJR episode quality be achieved for reconciliation payments to be made is important to protect beneficiaries from excessive reductions in utilization that may result from the financial incentives in an episode payment model to lower actual episode spending. Under the pay-for-performance methodology of the CJR model, this policy should encourage participant hospitals to focus on appropriate reductions or changes in utilization that lead to high quality, more efficient care. Based on current hospital quality measure performance, approximately ninety percent of participant hospitals would have a composite quality score of greater than or equal to 4.0 and be eligible for reconciliation payments based on acceptable or better quality performance.

Participant hospitals with an acceptable composite quality score of greater than or equal to 4.0 and less than 6.0 will be assigned to the ''Acceptable'' quality category and be eligible for a reconciliation payment if actual episode spending is less than the target price because their quality performance is at the acceptable level established for the CJR model. They will not be eligible for a quality incentive payment at reconciliation because their episode quality performance, while acceptable, is not good or excellent. Therefore, these hospitals will be eligible to receive a reconciliation payment if actual episode spending is less than the target price.

Participant hospitals with a good composite quality score of greater than or equal to 6.0 and less than or equal to 13.2 will be assigned to the ''Good'' quality category and be eligible for a quality incentive payment at reconciliation if actual episode spending is less than the target price because their quality performance exceeds the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they will be eligible for a quality incentive payment at reconciliation for good quality performance that equals 1.0 percent of the participant hospital's benchmark

price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR will either have less repayment responsibility (that is, the quality incentive payment will offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals will be eligible to receive a reconciliation payment if actual episode spending is less than the target price and will also receive a quality incentive payment.

Finally, hospitals with an excellent composite score quality score of greater than 13.2 will be assigned to the ''Excellent'' quality category and be eligible to receive a reconciliation payment if actual episode spending is less than the target price because their quality performance exceeds the acceptable level required for reconciliation payment eligibility under the CJR model. In addition, they will be eligible for a higher quality incentive payment at reconciliation for excellent quality performance that equals 1.5 percent of the participant hospital's benchmark price, thereby changing the effective discount percentage included in the target price experienced by the hospital at reconciliation. Thus, participant hospitals achieving this level of quality for LEJR episodes under CJR will either have less repayment responsibility (that is, the quality incentive payment will offset a portion of their repayment responsibility) or receive a higher payment (that is, the quality incentive payment would add to the reconciliation payment) at reconciliation than they would have otherwise based on a comparison of actual episode spending to the target price that reflects a 3.0 percent discount. Therefore, these hospitals will be eligible to receive a reconciliation payment if actual episode spending is less than the target price and would also receive a quality incentive payment.

TABLE 19—PERFORMANCE YEAR 1: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

| Composite quality score | Quality category | Eligible for reconciliation payment | Eligible for quality incentive payment | Effective discount percentage for reconciliation payment (%) | Effective discount percentage for repayment amount |
|---|---|---|---|---|---|
| <4.0 | Below Acceptable | No | No | 3.0 | Not applicable. |
| ≥4.0 and <6.0 | Acceptable | Yes | No | 3.0 | Not applicable. |
| ≥6.0 and ≤13.2 | Good | Yes | Yes | 2.0 | Not applicable. |
| >13.2 | Excellent | Yes | Yes | 1.5 | Not applicable. |

TABLE 20—PERFORMANCE YEARS 2 AND 3: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

| Composite quality score | Quality category | Eligible for reconciliation payment | Eligible for quality incentive payment | Effective discount percentage for reconciliation payment (%) | Effective discount percentage for repayment amount |
|---|---|---|---|---|---|
| <4.0 | Below Acceptable | No | No | 3.0 | 2.0 |
| ≥4.0 and <6.0 | Acceptable | Yes | No | 3.0 | 2.0 |
| ≥6.0 and ≤13.2 | Good | Yes | Yes | 2.0 | 1.0 |
| >13.2 | Excellent | Yes | Yes | 1.5 | 0.5 |

TABLE 21—PERFORMANCE YEARS 4 AND 5: RELATIONSHIP OF COMPOSITE QUALITY SCORE TO RECONCILIATION PAYMENT ELIGIBILITY AND THE EFFECTIVE DISCOUNT PERCENTAGE EXPERIENCED AT RECONCILIATION

| Composite quality score | Quality category | Eligible for reconciliation payment | Eligible for quality incentive payment | Effective discount percentage for reconciliation payment (%) | Effective discount percentage for repayment amount |
|---|---|---|---|---|---|
| <4.0 | Below Acceptable | No | No | 3.0 | 3.0 |
| ≥4.0 and <6.0 | Acceptable | Yes | No | 3.0 | 3.0 |
| ≥6.0 and ≤13.2 | Good | Yes | Yes | 2.0 | 2.0 |
| >13.2 | Excellent | Yes | Yes | 1.5 | 1.5 |

Under this methodology, the final stop-loss and stop-gain limits discussed in section III.C.8. of the final rule will not change for participant hospitals in different quality categories. Despite the limited number of quality measures adopted for the CJR model at this point in time compared to other programs, such as the Shared Savings Program and HBVP Program that use more measures in a quality scoring methodology, after considering the public comments we believe this approach to quality incentive payments based on the composite quality score will have the effect of increasing the alignment of the financial and quality performance incentives under the CJR model to the potential benefit of participant hospitals and their collaborators as well as CMS, although it substantially increases the

complexity of the pay-for-performance methodology to link quality and payment. The final methodology also provides a framework for incorporating quality performance and quality improvement in the pay-for-performance methodology of the CJR model as additional measures become available for consideration for the CJR model. We refer readers to section III.D.3. of this final rule for discussion of future measures for the model.

*Comment:* Many commenters urged CMS to provide incentives for hospitals to continuously improve the quality of care under the model. The commenters asserted that scoring approaches incorporating improvement have been successfully used in other CMS programs, such as the Shared Savings Program and HVBP Program, as well as other Innovation Center payment models. The commenters recommended that the proposed thresholds for reconciliation payment eligibility were inadequate as they would provide no incentive for further quality improvement for the approximately 50 percent of participant hospitals currently performing better than the proposed thresholds on all three proposed quality measures. Some of these commenters favored the composite quality score methodology and further recommended that in addition to incorporating quality performance on the quality measures in the CJR model payment methodology through the composite quality score, CMS should reward year-over-year quality improvement, like the Shared Savings Program.

A few commenters recommended that CMS reward quality improvement under the CJR model as long as there is no increase in episode spending, observing that under the statutory authority for the CJR model, one of the three expectations for a model is that it would increase the quality of care without increasing spending. The commenters claimed that setting a target price that always includes a discount over expected episode spending should not be necessary for participant hospitals that demonstrate improvements in quality performance.

*Response:* We appreciate the perspectives of the commenters who recommended that we directly reward hospitals for quality improvement, consistent with pay-for-performance policies under other CMS programs such as the HVBP Program and the Shared Savings Program. We note that the proposed pay-for-performance quality threshold methodology would have provided no additional potential for financial reward for quality improvement once participant hospitals met the 30th performance percentile threshold for reconciliation payment eligibility in the first three performance years and the 40th performance percentile threshold in the fourth and fifth performance years on the three proposed quality measures. As some commenters pointed out, the proposal was unlikely to advance a major goal of the CJR model to continue to improve the quality or maintain current high quality of care for beneficiaries in LEJR episodes at all participant hospitals. In contrast, the composite quality score methodology that incorporates quality measure performance and that we finalized in the preceding response to public comments may indirectly reward quality improvement. Quality measure performance for a performance year within a higher performance decile than the prior performance year may result in a higher number of quality performance points for that measure and, ultimately, a higher composite quality score that may result in participant hospital assignment to a quality category that provides quality incentive payments or a higher amount of quality incentive payments than the prior performance year's lower composite quality score. However, without further refinement of the composite quality score methodology finalized previously, unlike the pay-for-performance methodology in other CMS programs such as the Shared Savings Program, the CJR model would not directly reward quality improvement in the scoring methodology, thereby providing a lesser incentive for quality improvement than directly including points for improvement in the composite quality score as recommended by some commenters.

As we stated earlier in this section, we are not yet certain in this model test what performance outcomes can be achieved under best practices. Therefore, we believe a refinement to the composite score methodology in order to drive quality improvement for participant hospitals that have historically lagged in quality performance on the CJR model quality measures is appropriate, to supplement the composite score's valuing of quality performance in the pay-for-performance methodology of the model. We agree with the commenters that we should directly reward quality improvement under the CJR model pay-for-performance methodology to encourage participant hospitals currently at all levels of quality performance to improve their performance as they strive to achieve high quality performance outcomes under best practices. Like the commenters, we recognize that the heightened focus on episode cost and quality performance by participant hospitals may lead to substantial year-over-year quality measure improvement over the model performance years, and we agree that improvement should be valued in the pay-for-performance methodology, in addition to the quality measure performance percentile actually achieved by the hospital. However, we disagree with the commenters who suggested that participant hospitals demonstrating quality improvement should not be expected to demonstrate episode cost efficiency in order for quality improvement to be rewarded. Improved quality performance and cost savings are closely linked in the CJR pay-for-performance methodology, as both are major goals of the CJR model.

Therefore, we will refine the composite score methodology discussed in the proposed rule that assigns quality performance points based on performance percentiles for each measure to add the potential for incremental quality improvement points to be awarded for substantial improvement in performance on a required quality measure. We believe that the actual level of quality performance achieved should be most highly valued in the composite quality score to reward those hospitals furnishing high-quality care to CJR model beneficiaries, with a smaller contribution to the composite quality score made by improvement points if measure result improvement is achieved. We acknowledge that just because a hospital shows substantial improvement on a measure result, this does not necessarily mean the episode care is high-quality, yet the improvement spurred by the hospital's participation in the CJR model deserves to be valued as the hospital's performance is moving in a direction that is good for the health of beneficiaries. Valuing improvement is especially important because the CJR model involves such a wide range of hospitals that must participate if they are located in the selected MSAs, and the hospitals will be starting from many different current levels of quality performance. This refinement to the composite quality score methodology will help to provide all participant hospitals with a strong incentive to improve LEJR episode outcomes, including those hospitals with historically lagging quality performance.

Specifically, we will add into the composite quality score 10 percent of the maximum value for one or both of

the required measures, as applicable, which would equal 1 point for the THA/TKA Complications measure (NQF #1550) or 0.8 point for the HCAHPS Survey measure (NQF #0166), for those participant hospitals that demonstrate substantial improvement from the prior year's measure performance percentile on that measure. This modest increment of 10 percent will allow us to continue to value most significantly quality performance in the composite quality score, while incorporating a significant but lesser value on quality improvement. We believe that rewarding improvement by allocating 10 percent of the maximum quality performance points to improvement on a measure provides a significant incentive for participant hospitals to achieve national high performance benchmarks on the quality measures, as well as provides an incentive for historically lagging hospitals to make significant quality improvements.

Because of the uncertainty of statistical measures, as discussed previously in this section, and our annual comparison of a participant hospital's measure result to the national distribution to determine the hospital's performance percentile, we will only award measure quality improvement points where improvement is substantial and reflective of true improvement in quality performance on the individual measure. Thus, in order to be considered for improvement points on one of the measures, a participant hospital must have had a reportable measure performance result for that measure in the prior year. We note that in considering quality improvement points for award in the first model performance year, we will use measure results from the prior year quality measure performance period in determining each participant hospital's measure performance percentile against which we will compare its measure performance percentile for CJR model performance year 1 to determine if quality improvement points should be awarded. For the HCAHPS Survey measure (NQF #0166), the prior year quality measure performance period used will be July 1, 2014 through June 30, 2015. For the THA/TKA Complications measure (NQF #1550), the prior year quality measure performance period used will be April 1, 2012 through March 31, 2015. The measure performance percentiles for performance year 1 will be determined from measure results from the performance year 1 quality measure performance periods as displayed in Table C5 of this final rule.

We are defining substantial as improving 3 deciles or more in comparison to the national distribution of measure results. Improvement of three deciles represents a quality measure result change of over one-third of the range between the 10th percentile and the 90th percentile measure results. The 3 decile threshold to define substantial improvement is based on historical *Hospital Compare* information demonstrating that improving three deciles in measure performance on an annual basis is a challenging but attainable threshold for hospitals and reflects true improvement in quality performance on the individual measure. We estimate based on current quality measure performance over the most recent two years of available quality measure result data that 30 and 55 participant hospitals would qualify for improvement points on the HCAHPS Survey measure (NQF #0166) and the THA/TKA Complications measure (NQF #1550), respectively.

We note that when a participant hospital is awarded improvement points in addition to performance points on a specific required measure, the sum of these points for the measure will be slightly greater than the measure performance points that would be awarded to a hospital in the performance decile that is one level higher than the participant hospital's actual performance decile. By recognizing quality performance in the CJR model pay-for-performance methodology, supplemented by valuing quality improvement, we believe participant hospitals at all current levels of quality performance, including those historically lagging, will have the greatest incentives to achieve high and/or improved quality of care under the CJR model through strong financial incentives that are linked to quality.

*Comment:* A number of commenters urged CMS to further reduce the CJR model discount percentage in the target price for those participant hospitals who successfully reported THA/TKA voluntary PRO and limited risk variable data. They recommended that CMS apply a discount of 1.5 percent, rather than the proposed 1.7 percent, to the target price in order to support a participant hospital's development of an effective and efficient process for reporting. A commenter requested that CMS provide a stronger financial incentive for THA/TKA PRO voluntary and limited risk variable data submission as well as compensation for the additional hospital costs of data collection, reasoning that because the proposal for the reduced discount percentage only covers the expected additional costs of data collection, no financial incentive is present for hospitals to report these data. Several commenters stated that CMS should go further and require the submission of THA/TKA voluntary PRO and limited risk variable data by participant hospitals in order for reconciliation payments to be paid because, while limiting structure and process measures to value more highly outcome measures is laudable, the most important consideration in quality outcomes for CJR model beneficiaries should be beneficiary functional status. The commenters expressed disappointment in CMS' proposal that reporting would be voluntary and urged CMS to institute pay-for-reporting for these data are a requirement for hospitals to be paid any savings achieved for their episodes beyond the target price. Many commenters encouraged CMS to incorporate patient-reported outcomes measure performance in the CJR model as soon as possible, and some commenters further recommended that CMS delay implementation of the model until the PRO measure is available for use.

*Response:* We appreciate the emphasis the commenters placed upon measure development and implementation to capture the functional status of beneficiaries following LEJR procedures. Patient-reported outcomes following elective THA and TKA, which are the focus of the measure under development, are critically important for these costly procedures that beneficiaries choose to improve their quality of life, despite the lengthy recovery period involved. Pay-for-performance in the CJR model, an episode payment model that is designed to incentivize efficient, high-quality episode care, will benefit greatly from the incorporation of participant hospital performance on a measure of functional status when it is fully developed. We refer readers to section III.D.3.a.(9) of this final rule for further discussion of our plans and timeline to incorporate the THA/TKA Patient-Reported Outcome Performance Measure (PRO–PM) result in the CJR model when its development is complete after the period of THA/TKA voluntary PRO and limited risk variable data submission under the CJR model. We do not believe it would be appropriate to delay implementation of the CJR model until the measure has completed development, because the other final measures adopted for the model, as described in section III.D.2.a. through c. of this final rule, are meaningful measures of LEJR episode quality and

the CJR model provides an unprecedented opportunity to complete development of the THA/TKA PRO–PM because of the broad scope of the model test.

Because the measure is currently under development, we believe our final model payment policies and future plans for use of the measure result in the CJR model provide sufficient incentive and increased financial opportunity to encourage robust reporting by participant hospitals of THA/TKA voluntary PRO and limited risk variable data. For the reasons discussed earlier in this section, we are not finalizing our proposed pay-for-performance threshold methodology to determine a participant hospital's reconciliation payment eligibility if episode savings are achieved beyond the target price. Therefore, we are not finalizing our proposal to reduce the discount percentage to 1.7 percent from 2.0 percent for successful submission of THA/TKA voluntary PRO and limited risk variable data. Instead, under our final policy we are incorporating the successful criterion for submission of THA/TKA voluntary PRO and limited risk variable data into our composite quality score methodology for the CJR model, awarding points to participant hospitals who successfully submit these data that will be added into the calculation of the hospital's composite quality score, consistent with our discussion of the alternative approach to linking quality and payment in the proposed rule as described in detail earlier in this section. We refer readers to section III.D.3.a.(9) of this final rule for our final definition of successful reporting of THA/TKA voluntary PRO and limited risk variable data for each performance year of the CJR model. Furthermore, as the PRO–PM remains under development, we will not require the reporting of THA/TKA voluntary PRO and limited risk variable data for reconciliation payment eligibility. However, the successful reporting of the voluntary data may increase a participant hospital's financial opportunity under the model, which may be greater than the hospital's increased administrative cost to report the data. While the final policy to incorporate successful reporting of THA/TKA voluntary PRO and limited risk variable data into the composite quality score methodology is not directly keyed to addressing the hospital resources required for reporting as would have been true for the voluntary reporting payment adjustment that we proposed, we note that voluntary reporting can only help a hospital qualify for quality incentive payments and unsuccessful reporting will not hurt a participant hospital's eligibility for reconciliation payments.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our proposal discussed in section III.C.5.b.(5)(b) of this final rule to assign participant hospital required outcome measure point estimates to performance percentiles based on the national distribution. We summarize the public comments we received on the proposed criteria for successfully reporting the voluntary THA/TKA data, as discussed in section III.C.5.b.(5)(b) of this final rule, and provide our responses in section III.D.3.a. of this final rule. However, we are not finalizing our proposal discussed in section III.C.5.b.(5)(c)(iii) of this final rule of a pay-for-performance methodology that identifies specific performance thresholds for the required quality measures that must be met for reconciliation payment eligibility. We are also not finalizing our proposal discussed in section III.C.5.b.(2) of this final rule to reduce the discount factor included in the target price for successful submission of THA/TKA voluntary PRO and limited risk variable data. Instead, based on our review of the public comments, we are finalizing the use of a composite quality score, as discussed in section III.C.5.b.(5)(c)(ii) of this final rule, that is based on quality performance and improvement on the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0116), as well as submission of THA/TKA voluntary PRO and limited risk variable data, and places participant hospitals in one of four quality categories for each performance year, ''Below Acceptable,'' ''Acceptable,'' ''Good,'' and ''Excellent.'' The final payment policies for the quality categories for the CJR model performance years are discussed earlier in this section and displayed in Tables 19, 20, and 21. We summarize the public comments we received on the proposed applicable time period, as discussed in section III.C.5.b.(4) of this final rule, and provide our responses in section III.D.3.d. of this final rule. We also summarize the public comments we received on the reporting time period for the THA/TKA patient reported outcome and limited risk variable data discussed in section III.C.5.b.(4) of this final rule and provide our responses in section III.D.3.a.(8) of this final rule.

We have added new definitions to § 510.2, specifically: ''Composite quality score'' means a score computed for each participant hospital to summarize the hospital's level of quality performance and improvement on specified quality measures, as described in § 510.315; ''Quality performance points'' are points that CMS adds to a participant hospital's composite quality score for a measure based on the performance percentile scale and for successful data submission of patient reported outcomes; and ''Quality improvement points'' are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the previous performance year by at least three deciles on the performance percentile scale. We have revised § 510.305(f)(2) and (g)(2) and (3) to reflect the role of the composite quality score in determining reconciliation payment eligibility. The final pay-for-performance methodology is set forth in § 510.315, which has been retitled, ''Composite quality scores for determining reconciliation payment eligibility and quality incentive payments,'' and revised to set forth the final pay-for-performance methodology of the CJR model as described in this final rule.

6. Process for Reconciliation

We outlined in the proposed rule our proposals for how we intend to reconcile aggregate related Medicare payments for a hospital's beneficiaries in CJR episodes during a performance year against the applicable target price in order to determine if reconciliation payment (or repayment, beginning in performance year 2) is applicable under this model. We refer readers to section III.B. of this final rule for our definition of related services for LEJR episodes under CJR, to section III.C.2.a. of this final rule for our definition of performance years, and to section III.C.4. of this final rule for discussion of our approach to establish target prices.

a. Net Payment Reconciliation Amount (NPRA)

The proposed rule detailed our proposal to conduct reconciliation by calculating a NPRA for each hospital participant in the model. After the completion of a performance year, we proposed to retrospectively calculate a participant hospital's actual episode performance based on the episode definition. We noted that episode payments for purposes of the CJR model would exclude the effects of special payment provisions under existing Medicare payment systems (section III.C.3.a. of this final rule), be subject to

proration for services that extend beyond the episode (section III.C.3.b. of this final rule), and exclude certain PBPM payments for programs and models specified in section III.C.7.d. of this final rule. We proposed that some episodes may be excluded entirely from the CJR model due to overlap with BPCI episodes, as discussed in section III.C.7.b. of this final rule. Finally, we proposed that actual episode payments calculated for purposes of CJR would be capped at anchor MS–DRG and region-specific high episode payment ceilings (section III.C.3.c. of this final rule). We proposed to apply the high episode payment ceiling policy to episodes in the performance year similarly to how we apply it to historical episodes (section III.C.4.c. of this final rule). Episode payments for episodes attributed to CJR eligible hospitals would be determined and the high episode payment ceiling would be calculated as two standard deviations above the mean. Any actual episode payment amount above the high payment ceiling would be capped at the applicable ceiling.

We proposed to compare each participant hospital's actual episode payment performance to its target prices. We proposed that, as discussed in section III.C.4. of this final rule, a participant hospital would have multiple target prices for episodes ending in a given performance year, based on the MS–DRG anchor (MS–DRG 469 versus MS–DRG 470), the performance year when the episode was initiated, when the episode was initiated within a given performance year (January 1 through September 30 of the performance year, October 1 through December 31 of the performance year, October 1 through December 31 of the prior performance year), and whether the participant hospital successfully submitted THA/TKA voluntary PRO and limited risk variable data. The applicable target price for each episode would be determined using the previously stated criteria, and the difference between each CJR episode's actual payment and the relevant target price (calculated as target price subtracted by CJR actual episode payment) would be aggregated for all episodes for a participant hospital within the performance year, representing the raw NPRA. This amount would be adjusted per the steps discussed later in this section, creating the NPRA.

We proposed to adjust the raw NPRA to account for post-episode payment increases (section III.C.8.e. of this final rule) and stop-loss and stop-gain limits (section III.C.8.b. of this final rule). Any NPRA amount greater than the proposed stop-gain limit would be capped at the stop-gain limit, and any NPRA amount less than the proposed stop-loss limit would be capped at the stop-loss limit.

We did not propose to include any CJR reconciliation payments or repayments to Medicare under this model for a given performance year in the NPRA for a subsequent performance year. We want to incentivize providers to provide high quality and efficient care in all years of the model. If reconciliation payments for a performance year are counted as Medicare expenditures in a subsequent performance year, a hospital would experience higher Medicare expenditures in the subsequent performance year as a consequence of providing high quality and efficient care in the prior performance year, negating some of the incentive to perform well in the prior year. Therefore, we proposed to not have the NPRA for a given performance year be impacted by CJR repayments or reconciliation payments made in a prior performance year. For example, if a CJR hospital receives a $10,000 reconciliation payment in the second quarter of 2017 for achieving episode spending below the target price for performance year 1, that $10,000 reconciliation payment amount would not be included in the performance year 2 calculations of actual episode spending. However, as discussed in section III.C.6.b. of this final rule, during the following performance year's reconciliation process, we proposed to account for additional claims run-out and overlap from the prior performance year, and net that amount with the subsequent performance year's NPRA to determine the reconciliation or repayment amount for the current reconciliation. The following is a summary of comments received and our response.

*Comment:* Commenters emphasized the need to accurately account for wage index differences when calculating target prices and conducting reconciliation activities.

*Response:* We refer readers to comments and responses to comments in section III.C.4.b.(7) of this final rule for further discussion on the finalized target price calculation policy to normalize for wage index differences at the claim level and to reintroduce wage index differences based on the participant hospital's wage index and labor cost share. In order to maintain consistency with the target price calculations, and to more accurately normalize for the effects of wage index differences, we will apply the same claim-level wage index normalization to claim payments included in actual episode expenditures for each performance year when calculating a hospital's NPRA.

We also refer readers to response to comments in section III.C.4.b.(7) of this final rule on the importance of reintroducing wage index differences when calculating target prices and reconciliation and repayment amounts. In order to maintain consistency with the target price calculations, we will reintroduce wage index differences when calculating NPRA by applying the participant hospital's wage index and 0.7 as the labor cost share. By mirroring the target price calculation approach for accounting for wage index differences, we can better ensure that any reconciliation amounts or repayments to Medicare are due to differences in practice patterns, not Medicare FFS wage index policy variations.

*Comment:* A commenter suggested that CMS perform reconciliation calculations differently when a beneficiary in a CJR episode receives PAC from a SNF or HHA not recommended by the CJR hospital discharge planners. Another commenter noted that the reconciliation calculation CMS proposed needed refinement as it pertains to the proposed methodology for setting episode prices and paying model participants; the commenter's suggestions pertaining to the payment methodology are addressed in section III.C.4. of this final rule.

*Response:* We thank commenters for their suggestions. However, we do not believe it is appropriate to make adjustments to a given hospital's NPRA based on the choice of PAC facility for beneficiaries discharged from that facility. Such a change would be inconsistent with our goal of maintaining beneficiary choice and access to care, discussed in section III.F. of this final rule. We also note that the process for calculating the NPRA is consistent with our methodology for calculating target prices and actual episode spending during the performance period (section III.C.4.b. of this final rule), along with the adjustments to NPRA that would account for post-episode spending (III.C.8.d. of this final rule) and the stop-loss and stop-gain limits discussed in section III.C.8.b. of this final rule.

*Final Decision:* We refer readers to section III.C.4. of this final rule for discussion of modifications to how the target prices and performance period episode spending are calculated, including risk stratification for fracture patients. In addition, section III.C.5. of this final rule addresses our final policy on how quality performance will be

used to determine a CJR hospital's effective discount percentage. However, after consideration of the public comments we received, we are modifying our proposal to calculate the NPRA utilizing the methodology described in this subsection to account for wage index normalization and reintroduction when calculating actual episode expenditures in a performance year and including the modifications to calculation of target prices and actual episode spending as described elsewhere in this section. After the completion of a performance year, we will retrospectively calculate a participant hospital's actual episode spending based on the episode definition. Each participant hospital's actual episode payment performance will be compared to its target prices, creating the raw NPRA, and then adjusted for the stop-loss and stop-gain limits, as well as post-episode spending, creating the NPRA.

b. Payment Reconciliation

We proposed to reconcile payments retrospectively through the following reconciliation process. We proposed to reconcile a participant hospital's CJR actual episode payments against the target price 2 months after the end of the performance year. More specifically, we would capture claims submitted by March 1st following the end of the performance year and carry out the NPRA calculation as described previously to make a reconciliation payment or hold hospitals responsible for repayment, as applicable, in quarter 2 of that calendar year.

*Comment:* Some commenters explicitly supported CMS's proposal to implement a retrospective reconciliation process. However, a few commenters suggested CMS implement a prospective reconciliation process (see section III.C.2.b. of this final rule for discussion of comments on the retrospective payment methodology). Commenters suggested CMS make a prospective bundled payment to hospitals for all services provided during a CJR episode; hospitals would then distribute payments to other providers and suppliers. A commenter suggested that CMS hold a specified percentage of total episode payments for downstream (non-hospital) providers and suppliers furnishing services during CJR episodes and hospitals would later distribute the amount of the withheld payment to providers and suppliers based on quality and efficiency.

*Response:* We refer readers to section III.C.4.b. of this final rule for discussion of comments received on our proposed methodology to establish target prices and retrospectively calculate performance period episode spending.

We considered the suggestion to implement a blended reconciliation approach by withholding a specified percentage of FFS payments and later distributing the remainder of payments to hospitals for disbursement to downstream providers and suppliers. We believe that the operational challenges associated with such an approach would introduce significant administrative burden for hospitals. We also note that, as discussed in section III.C.10. of this final rule, we are finalizing policies that will allow participant hospitals to engage in financial arrangements and relationships with downstream providers and suppliers. We believe these relationships will allow participant hospitals the opportunity to share financial risk with downstream providers and suppliers and engage such entities in efforts to improve quality and efficiency throughout the episode.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, without modification, to conduct a retrospective reconciliation process for the CJR model.

To address issues of overlap with other CMS programs and models that are discussed in section III.C.7. of the proposed rule, we also proposed that during the following performance year's reconciliation process, we would calculate the prior performance year's episode spending a second time to account for final claims run-out, as well as overlap with other models as discussed in section III.C.7. of this final rule. This would occur approximately 14 months after the end of the prior performance year. As discussed later in this section, the amount from this calculation, if different from zero, would be applied to the NPRA for the subsequent performance year in order to determine the amount of the payment Medicare would make to the hospital or the hospital's repayment amount. We note that the subsequent reconciliation calculation would be applied to the previous calculation of NPRA for a performance year to ensure the stop loss and stop gain limits discussed in section III.C.8. of this final rule are not exceeded for a given performance year.

For the performance year 1 reconciliation process, we would calculate a participant's, as previously described, and if positive, the hospital would receive the amount as a reconciliation payment from Medicare. If negative, the hospital would not be responsible for repayment to Medicare, consistent with our proposal to phase in financial responsibility beginning in performance year 2. Starting with the CJR reconciliation process for performance year 2, in order to determine the reconciliation or repayment amount, the amount from the subsequent reconciliation calculation would be applied to the NPRA. We proposed that if the amount is positive, and if the hospital meets the minimum quality score required to be eligible for reconciliation, (discussed further in section III.C.5. of this final rule), the hospital would receive the amount as a reconciliation payment from Medicare. If the amount is negative, Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. Note that given our proposal to not hold participant hospitals financially responsible for repayment for the first performance year, during the reconciliation process for performance year 2 only, the subsequent calculation amount (for performance year 1) would be compared against the performance year 1 NPRA to ensure that the sum of the NPRA calculated for performance year 1 and the subsequent reconciliation calculation for year 1 is not less than zero. For performance years 2 through 5, though, we proposed that Medicare would hold the participant hospital responsible for repaying the absolute value of the repayment amount following the rules and processes for all other Medicare debts. The following table illustrates a simplified example of how the subsequent reconciliation calculation may affect the following year's reconciliation payment. The second column represents the raw NPRA calculated for Performance Year 1, meaning that Hospital A's aggregated episode spending was $50,000 below the target price multiplied by the number of episodes. The third column represents the subsequent reconciliation calculation, indicating that when calculating episode spending during Performance Year 1 a second time, we determined that Hospital A's aggregated episode spending was $40,000 below the target price multiplied by the number of episodes, due to claims runout, accounting for model overlap, or other reasons. The fourth column represents the difference between the subsequent reconciliation calculation and the raw NPRA calculated for Performance Year 1. This difference is then combined with the amount in the fifth column to create the reconciliation

payment amount for PY2, which is reflected in the sixth column.

TABLE 22—SAMPLE RECONCILIATION RESULTS

| | Performance Year 1 (2016) raw NPRA | Performance Year 1 subsequent reconciliation calculation | Difference between PY1 subsequent reconciliation calculation and raw NPRA | Performance Year 2 (2017) raw NPRA | Reconciliation payment made to hospital in quarter 2 2018 |
|---|---|---|---|---|---|
| Hospital A | $50,000 | $40,000 | ($10,000) | $25,000 | $15,000 |

This reconciliation process would account for overlaps between the CJR model and other CMS models and programs as discussed in section III.C.7. of this final rule, and would also involve updating performance year episode claims data. We also note that in cases where a hospital has appealed its quality performance results on the complications and HCAHPS quality measures through the IQR program appeal process, discussed in section III.D. of this final rule, and where such appeal results would result in a different effective discount percentage or quality incentive payment under the CJR model, the subsequent reconciliation calculation will account for these updates as well.

For example, for performance year 1 for the CJR model in 2016, we would capture claims submitted by March 1st, 2017, and reconcile payments for participant hospitals approximately 6 months after the end of the performance year in quarter 2 of calendar year 2017. We would carry out the subsequent calculation in the following year in quarter 2 of calendar 2018, simultaneously with the reconciliation process for the second performance year, 2017. Table 23 provides the reconciliation timeframes for the model. Lastly, we proposed that the reconciliation payments to or repayments from the participant hospital would be made by the MAC that makes payment to the hospital under the IPPS. This approach is consistent with BPCI Model 2 operations.

We proposed this approach in order to balance our goals of providing reconciliation payments in a reasonable timeframe, while being able to account for overlap and all Medicare claims attributable to episodes. We stated that pulling claims 2 months after the end of the performance year would provide sufficient claims run-out to conduct the reconciliation in a timely manner, given that our performance year includes episodes ending, not beginning, by December 31st. We note that in accordance with the regulations at § 424.44 and the Medicare Claims Processing Manual (Pub. L. 100–04), Chapter 1, Section 70, Medicare claims can be submitted no later than 1 calendar year from the date of service. We recognized that by pulling claims 2 months after the end of the performance year to conduct reconciliation, we would not have complete claims run-out. However, we believed that the 2 months of claims run-out would be an accurate reflection of episode spending and consistent with the claims run-out timeframes used for reconciliation in other payment models, such as BPCI Models 2 and 3. The alternative would be to wait to reconcile until we have full claims run out 12 months after the end of the performance year, but we were concerned that this approach would significantly delay earned reconciliation payments under this model. Because we proposed to conduct a second calculation to account for overlap with other CMS models and programs, we proposed to incorporate updated claims data with 14 months run out at that time. However, we did not expect that the updated data should substantially, in and of itself, affect the reconciliation results assuming hospitals and other providers and suppliers furnishing services to Medicare beneficiaries in CJR episodes follow usual patterns of claims submission and do not alter their billing practices due to this model.

TABLE 23—PROPOSED TIMEFRAME FOR RECONCILIATION IN CJR

| Model performance year | Model performance period | Reconciliation claims submitted by | Reconciliation payment or repayment | Second calculation to address overlaps and claims run-out | Second calculation adjustment to reconciliation amount |
|---|---|---|---|---|---|
| Year 1 * | Episodes ending April 30, 2016 to December 31, 2016. | March 1, 2017 | Q2 2017 | March 1, 2018 | Q2 2018. |
| Year 2 | Episodes ending January 1, 2017 through December 31, 2017. | March 1, 2018 | Q2 2018 | March 1, 2019 | Q2 2019. |
| Year 3 | Episodes ending January 1, 2018 through December 31, 2018. | March 1, 2019 | Q2 2019 | March 2, 2020 | Q2 2020. |
| Year 4 | Episodes ending January 1, 2019 through December 31, 2019. | March 2, 2020 | Q2 2020 | March 1, 2021 | Q2 2021. |
| Year 5 | Episodes ending January 1, 2020 through December 31, 2020. | March 1, 2021 | Q2 2021 | March 1, 2022 | Q2 2022. |

* Note that the reconciliation for Year 1 would not include repayment responsibility from CJR hospitals.

*Comment:* Several commenters supported the proposed reconciliation process. However, many commenters requested that CMS conduct reconciliation activities on a quarterly or semi-annual, instead of annual, basis. Some commenters suggested that CMS offer participant hospitals the option of electing annual or a more frequent reconciliation timeline. Commenters stated numerous reasons for their request, including: Providing revenue and cash flow to hospitals throughout the year to aid in care coordination and redesign efforts; giving hospitals interim data on financial performance; the time lag between the end of a performance year and the subsequent reconciliation calculation; utilizing data for improving care processes; giving hospitals the opportunity to gainshare with other providers and suppliers with greater frequency; and consistency with the frequency of reconciliation in the BPCI initiative, among other reasons. Some commenters supported the proposal to make reconciliation payments or require repayment on an annual basis, but requested that CMS also conduct interim quarterly reconciliation projections to provide hospitals with information on financial performance throughout the performance year. Several commenters claimed that the proposed reconciliation process would result in reduced revenue for hospitals throughout the performance period. However, a commenter stated that receiving annual reconciliation results in the second quarter of the calendar year following the completion of a performance year would provide hospitals with timely feedback and opportunity to adjust strategies in subsequent years to improve or maintain financial performance. Another commenter noted that annual reconciliation at the end of each performance year would give participants an early indication of progress under the model.

*Response:* We appreciate the perspectives of the commenters on our proposal. In response to commenters' concerns that an annual reconciliation process would result in reduced revenue for hospitals, we are clarifying that model participants, and all providers and suppliers, would continue to bill and be paid through normal Medicare FFS processes throughout the model for Part A and Part B services furnished to beneficiaries during a CJR episode, with a retrospective reconciliation process after the conclusion of a performance year. We disagree that an annual reconciliation process would result in reduced revenue for hospitals. In addition, we note that beginning in the second quarter of 2017 when the first reconciliation is performed, CJR hospitals will be able to utilize any reconciliation payments they earn to invest in care redesign and coordination efforts on an ongoing basis. We emphasize that the delay of financial repayment responsibility until performance year 2 means no hospital will be required to make a repayment to Medicare until the second quarter of 2018 for actual episode spending exceeding the target price. In addition, the delay of the model start date until April 1, 2016 and truncated first performance year will reduce the amount of time between beginning participation in the CJR model and the first reconciliation.

We appreciate commenters' concerns and request for more frequent feedback on performance throughout the performance period. However, we continue to believe that an annual reconciliation process is most appropriate for the following reasons. As previously stated in this section, providers and suppliers have a calendar year to submit FFS claims for payment. Implementing a quarterly reconciliation process, as we do for the BPCI models, would mean that many claims may be incomplete at the time of the reconciliation. The BPCI reconciliation process incorporates 3 subsequent reconciliation calculations, and BPCI participants have experienced significant fluctuation in financial results between the initial reconciliation and the subsequent calculations. We believe our proposed annual reconciliation approach will lead to more stable financial results for providers. We also note based on our experience with the BPCI models that a quarterly reconciliation process results in model participants' near constant engagement in the reconciliation and appeals processes. This can potentially take time away from efforts focused on care redesign and coordination with providers and suppliers engaged in furnishing care for beneficiaries under the model. In addition, given our plan to assess hospital performance on quality measures (discussed in section III.C.5. of this final rule), we note that annual reconciliation processes will be necessary in order to calculate an accurate composite quality score for hospital participants, since quality measures are calculated on an annual basis. We also proposed to perform annual reconciliation for consistency with other models and programs such as the Shared Savings Program. As discussed in section III.C.7.e.of this final rule, we will allow for beneficiaries to be assigned to an ACO and have a concurrent CJR episode. We will perform our reconciliation calculations and then make the reconciliation and repayment amounts available to other models and programs in order to account for overlapping beneficiaries. We have aligned our annual reconciliation timeline with the ACO models and program in order to make this information available before the ACO models and program begin their annual financial reconciliation calculations; such a timeline is necessary to be able to account for program and model overlap.

We understand commenters' assertions that annual reconciliation does not allow for frequent feedback on financial performance under the model. We would like to reiterate that we will be providing both line-level and summary claims data to model participants on a quarterly basis, as discussed in section III.E. of this final rule. Such data are intended to provide hospitals with information about their care patterns and to identify opportunities for care redesign and savings. This data will also provide ongoing feedback to hospitals about their performance under the model, by including both raw claims as well as summary data with information about their episode spending and care patterns. Moreover, unlike in BPCI Models 2 and 3, we will be providing model participants with performance year target prices on a prospective basis, as discussed in section III.C.4 of this final rule. Prospective target pricing will provide hospitals with increased certainty about financial targets under the model. Finally, we also considered commenters' requests to conduct interim financial reconciliation calculations on a quarterly basis and provide the results of such calculations to hospitals. Because of the potential for volatility between the interim results and the final reconciliation results, and our concern that such results would not provide additional meaningful information to hospitals not present in the claims data and prospective target prices, we are not pursuing an interim reconciliation process at this time. However, we will continue to consider commenters' suggestions and will consider the feasibility of providing interim results in the future if we believe it could aid hospitals in succeeding under this model and would provide additional information not already present in the previously stated claims data and target prices.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, without modification, to conduct financial reconciliation on an annual basis. We will engage with CJR hospitals throughout the model to ensure the prospective target prices and quarterly data provided to hospitals provide sufficient ongoing feedback and data to hospitals between reconciliations. As previously noted, we will continue to consider commenters' suggestions and consider the feasibility of further interim financial results in the future if warranted.

*Comment:* Several commenters expressed concerns about post-payment denials and Recovery Audit Contractor (RAC) or MAC reviews that may occur after the CJR model reconciliation processes are complete. A commenter asserted that providers could be doubly penalized for such claims if review and denial occurs after the subsequent reconciliation calculation, in particular if a claim is denied for more than 100 percent of the payment amount. The commenter noted further concern due to the aggregated reconciliation calculation; that is if a given claim is later denied for an amount greater than 100 percent of the payment amount, the denied amount could affect more than just the claim in question. The commenter urged CMS to exempt all claims attributed to the CJR model from post-payment review and denial.

Another commenter requested that CMS further outline the reconciliation and repayment processes, including how reconciliation would be conducted for Periodic Interim Payment (PIP) hospitals. Finally, a commenter requested a more flexible repayment process for hospitals meeting certain eligibility criteria, but did not suggest specific criteria.

*Response:* We appreciate the commenters' views. We believe the proposed process to perform a reconciliation calculation 2 months after the conclusion of a performance year, with a subsequent reconciliation calculation 12 months later, will allow sufficient time for routine monitoring, review, and adjustment. We acknowledge that audits and reviews may occur after our reconciliation processes are complete, agreeing that post-payment reviews may occur up to 3 years after the submission of a claim, or longer in some instances. However, we believe that concluding reconciliation processes 14 months after the completion of a performance year provides a reasonable timeframe for claims run-out and subsequent actions on a claim and is consistent with other payment reconciliation processes, such as the reconciliation of hospital cost reports, which can have impacts that are mostly but not entirely reconciled across multiple payment systems. With respect to commenters' specific suggestions, we note that prohibiting review of all claims submitted for a beneficiary during a CJR episode would not be consistent with our stated goals of the model to monitor for quality and appropriateness of care. While we appreciate the concern that the price setting methodology under this model already provides a limit on spending during the episode, we point out that provider payments are not absolutely capped and hospitals are therefore not completely at risk. During the initial model period in which hospitals will not be financially responsible for repayment to Medicare for spending exceeding the target price, all risk will be borne by Medicare. In addition, in later years of the model all CJR hospital gains and losses are capped, as discussed in section III.C.8. of this final rule, meaning that Medicare will continue to bear risk for unusually costly cases. We do not believe that CMS should be denied the full flexibility to utilize all current processes for pre- and post-payment review based on existing rules and regulations for claims associated with care furnished under this model. Such a policy could potentially encourage inefficient or inaccurate billing practices, or hinder CMS' ability to appropriately monitor provider and supplier practices under the model. We also note that such situations would only happen if a claim were later denied and as such, encourage providers and suppliers submitting claims to ensure accuracy and that policies as laid out in this final rule are followed by all providers and suppliers submitting Medicare FFS claims for services furnished to beneficiaries under the model.

In response to these comments we have considered whether it would be appropriate to allow subsequent reconciliations if claims are denied and reprocessed after the second reconciliation. We do not believe this is appropriate for several reasons. First, we note that in the event that the hospital's total episode spending exceeded the target price, we are finalizing policies that limit hospitals' financial responsibility for such spending, as discussed in section III.C.8. of this final rule. Second, the entire purpose of MAC and RAC audits is to ensure that Medicare payments are correctly administered and made only for services delivered in accordance with statute and regulation. If the hospital enters into appropriate collaboration agreements with high quality, responsible, and compliant PAC providers, the 14-month period prior to the second reconciliation provides ample opportunity for the hospital and its collaborators to work together to conduct internal audits and ensure that PAC claims are properly submitted or corrected. We believe it is appropriate for hospitals to continue to share some risk with Medicare even after the final reconciliation, and believe this provides additional incentives for them to work closely with their collaborators to ensure that all services are delivered appropriately. Third, we believe it is important to conclude the reconciliation process in the timeframe we have previously outlined in this section, in order to provide hospitals with financial results and certainty over their performance under the model. Additional subsequent reconciliations could introduce uncertainty for model participants. Finally, we do agree that we have a responsibility to ensure that MACs, RACs, and other auditing entities audit services delivered under the CJR using the rules and regulations governing the CJR model in addition to all other relevant statute, regulation, and guidance. We believe that appropriate contractor training and oversight will protect hospitals from inappropriate denials while protecting beneficiaries from the use of inappropriate services and protecting Medicare from making payments on inappropriate claims. We reiterate the information provided in the proposed rule that when a hospital is eligible for a reconciliation payment, such payment would be made to participant hospitals in a form and manner specified by CMS. In cases where repayment is required, as stated in the proposed rule, CMS will follow the normal Medicare debt processes, such as issuing a demand letter. CMS intends to build on existing processes for making reconciliation payments to hospitals or requiring repayment which are familiar to hospitals. Such processes will rely on electronic and other established processes to the extent possible. We also reiterate that as discussed in section III.C.8. of this final rule, certain hospitals would be afforded additional financial protections. We believe are protections are sufficient and an extended repayment process for such hospitals is not necessary.

With regard to PIP hospitals, we appreciate that commenters point out the different payment processes that apply to such hospitals. PIP hospitals receive biweekly payments based on

hospitals' estimates of applicable Medicare reimbursement for a given cost period. Such hospitals also submit FFS claims to Medicare, which are reconciled against the payments made through the PIP processes. Given that such hospitals continue to submit FFS claims and the reconciliation and repayment amounts from the CJR model would not be included in the PIP hospital cost reports at settlement, we do not believe it is necessary to institute a separate reconciliation process for PIP hospitals.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our proposal to calculate the NPRA as previously outlined. We are also finalizing, without modification, our proposal to conduct an annual retrospective reconciliation with one subsequent reconciliation calculation in the following year.

The following table illustrates the final timeframe for reconciliation.

TABLE 24—FINAL TIMEFRAME FOR RECONCILIATION IN CJR

| Model performance year | Model performance period | Reconciliation claims submitted by | Reconciliation payment or repayment | Second calculation to address overlaps and claims run-out | Second calculation adjustment to reconciliation amount |
|---|---|---|---|---|---|
| Year 1* | Episodes ending June 30, 2016 to December 31, 2016. | March 1, 2017 | Q2 2017 | March 1, 2018 | Q2 2018. |
| Year 2 | Episodes ending January 1, 2017 through December 31, 2017. | March 1, 2018 | Q2 2018 | March 1, 2019 | Q2 2019. |
| Year 3 | Episodes ending January 1, 2018 through December 31, 2018. | March 1, 2019 | Q2 2019 | March 2, 2020 | Q2 2020. |
| Year 4 | Episodes ending January 1, 2019 through December 31, 2019. | March 2, 2020 | Q2 2020 | March 1, 2021 | Q2 2021. |
| Year 5 | Episodes ending January 1, 2020 through December 31, 2020. | March 1, 2021 | Q2 2021 | March 1, 2022 | Q2 2022. |

*Note that the reconciliation for Year 1 would not include repayment responsibility from CJR hospitals.

This final policy is set forth at § 510.305.

7. Adjustments for Overlaps With Other Innovation Center Models and CMS Programs

a. Overview

In the proposed rule, we acknowledged that there may be circumstances where a Medicare beneficiary in a CJR episode may also be assigned to an ACO participating in the Shared Savings Program or otherwise accounted for in a payment model being tested by the Innovation Center. Current or forthcoming programs and models with potential overlap with CJR are displayed in Table 24. For purposes of this final rule, ''total cost of care'' models refers to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. We use the term ''shared savings'' to refer to models in which the payment structure includes a calculation of total savings and CMS and the model participants each retain a particular percentage of that savings. We note that there exists the possibility for overlap between CJR episodes and shared savings programs and models such as the Pioneer ACO Model, other total cost of care models such as the OCM, other Innovation Center payment models such as BPCI, and other models or programs that incorporate per-beneficiary-per-month fees or other payment structures.

TABLE 25—CURRENT PROGRAMS AND MODELS WITH POTENTIAL OVERLAP WITH CJR MODEL

| Program/model | Brief description | Shared savings? | Per-beneficiary-per-month (PBPM) payments? |
|---|---|---|---|
| Pioneer ACO Model | ACO shared savings model | Yes | No. |
| Medicare Shared Savings Program (Shared Savings Program). | ACO shared savings program | Yes | No. |
| Next Generation ACO Model* | ACO shared savings model | Yes | No. |
| Comprehensive Primary Care initiative (CPCi) | Pays primary care providers for improved and comprehensive care management. | Yes | Yes. |
| Multi-payer Advanced Primary Care Practice (MAPCP). | Multi-payer model for advanced primary care practices, or ''medical homes''. | Yes | Yes. |
| Bundled Payments for Care Improvement (BPCI) | Bundled payment program for acute or PAC services or both. | No | No. |
| Oncology Care Model (OCM)* | Multi-payer model for oncology physician group practices (PGPs). | No | Yes. |
| Comprehensive ESRD Care Initiative (CEC)* | ACO for ESRD Medicare beneficiaries | Yes | No. |
| Million Hearts* | Model targeting prevention of heart attack and stroke. | No | Yes. |

TABLE 25—CURRENT PROGRAMS AND MODELS WITH POTENTIAL OVERLAP WITH CJR MODEL—Continued

| Program/model | Brief description | Shared savings? | Per-beneficiary-per-month (PBPM) payments? |
|---|---|---|---|
| Medicare Care Choices Model (MCCM)* ..... | Hospice concurrent care model ..... | No ..... | Yes. |

*Denotes model in pre-implementation phase.

In the proposed rule, we outlined the following issues that may arise in such overlap situations that must be addressed under CJR. First, beneficiaries in CJR episodes could also be part of BPCI Model 2 or 3 LEJR episodes or BPCI non-LEJR episodes, and the clinical services provided as part of each episode may overlap entirely or in part. Second, CJR reconciliation payments and repayments that are made under Part A and B and attributable to a specific beneficiary's episode may be at risk of not being accounted for by other models and programs when determining the cost of care under Medicare for that beneficiary. Third, some Innovation Center models make PBPM payments to entities for care coordination and other activities, either from the Part A or B Trust Fund or both, or from the Innovation Center's own appropriation (see section 1115A(f) of the Act). These payments may occur during a CJR episode. Finally, there could be instances when the expected Medicare savings for a CJR beneficiary's episode (represented by the discount percentage) is not achieved by Medicare because part of that savings is paid back to the hospital or another entity under the Shared Savings Program or a total cost of care model in which the beneficiary is also included. We sought comment on our proposals to account for overlap with the Shared Savings Program and other models, including those listed in Table 24 as well as other CMS models or programs.

The following is a summary of the comments received and our responses.

*Comment:* A commenter requested that CMS not limit providers from developing and implementing other episode-based payment models while participating in the CJR model.

*Response:* We clarify that we have not included any limitations on participation in future or current models through this final rule. In addition, we have included the policies in this section in order to allow for CJR hospitals to participate in other models and initiatives concurrently with the CJR model.

b. CJR Beneficiary Overlap With BPCI Episodes

BPCI is an episode payment model testing LEJR episodes, as well as 47 other episodes, in acute or PAC or both settings (Models 1, 2, 3 or 4). As discussed in section III.A. of the proposed rule, we proposed to exclude from selection for participation in the CJR payment model those geographic areas where 50 percent or more of LEJR episodes are initiated at acute care hospitals testing the LEJR episode in BPCI in Models 1, 2 or 4 as of July 1, 2015. In that same section, we proposed that acute care hospitals in selected geographic areas participating in BPCI under Model 1 (acute care only) and those participating as episode initiators for the LEJR episode in Model 2 (acute and PAC from 30 to 90 days post-discharge) or Model 4 (prospective episode payment for the LEJR anchor hospitalization and related readmissions for 30 days post-discharge) be excluded from CJR. We discuss the comments received on this proposal and our responses in section III.A.4. of this final rule.

While we believed these proposals will mitigate the overlap of CJR beneficiaries with BPCI episodes, there may still be instances of model overlap that we need to account for under CJR. These include circumstances when a beneficiary is admitted to a CJR participant hospital for an LEJR procedure where the beneficiary would also be in a BPCI Model 2 episode under a PGP that would initiate the episode under BPCI. In another example, a beneficiary discharged from an anchor hospitalization under CJR could enter a BPCI Model 2 LEJR episode at another hospital for a phased second joint replacement procedure or enter a BPCI Model 3 LEJR episode upon initiation of PAC services at a BPCI PAC provider episode initiator for the LEJR episode. Similarly, a beneficiary in a BPCI Model 2 or Model 3 LEJR episode could be admitted to a CJR participant hospital for a phased second joint replacement. In all such scenarios in which there is overlap of CJR beneficiaries with any BPCI LEJR episodes, we proposed that the BPCI LEJR episode under Models 1, 2, 3, or 4 take precedence and we would cancel (or never initiate) the CJR episode. Because the cancelation (or lack of initiation) would only occur for overlap with BPCI LEJR episodes, we expect that the participant hospital and treating physician would generally be aware of the beneficiary's care pathway that would cancel or not initiate the CJR episode. Therefore, we would exclude the CJR episode from the CJR participant hospital's reconciliation calculations where we compare actual episode payments to the target price under the CJR model. If we were to allow both CJR and BPCI LEJR episodes to overlap, we would have no meaningful way to apply the payment policies in two models with overlapping care redesign interventions and episodes. Participants in BPCI have an expectation that eligible episodes will be part of the BPCI model test, whereas CJR participants would be aware that episodes may be canceled when there is overlap with BPCI episodes as previously discussed in this final rule. We aim to preserve the integrity of ongoing model tests without introducing major modifications (that is, CJR episode precedence) that could make evaluation of existing models more challenging. We considered that there may also be instances of overlap between CJR and BPCI Model 3 LEJR episodes where our proposal to give precedence to all BPCI episodes could lead to undesirable patient steering because the BPCI Model 3 episode does not begin until care is initiated at an episode-initiating PAC provider. It could be possible for a participating CJR hospital to purposefully guide a beneficiary to a BPCI Model 3 LEJR episode initiating PAC provider to exclude that beneficiary's episode from CJR. We considered giving precedence to the CJR episode in overlap with Model 3 beneficiaries because the CJR episode begins with admission for the anchor hospitalization and thus includes more of the episode services. However, we believed the steering opportunities would be limited due to the preservation of beneficiary choice of provider in this model (as discussed in section III.E. of the proposed rule). As outlined in section III.F. of this final rule, CJR hospitals must provide patients with a complete list of all

available PAC options. Moreover, BPCI Model 3 PAC providers are actively involved in the decision to admit patients to their facilities. As episode initiators in BPCI, such providers are subject to monitoring and evaluation under that model and would be vigilant about not engaging in steering themselves or spurred by other providers. Nevertheless, we will monitor CJR hospitals to ensure steering or other efforts to limit beneficiary access or move beneficiaries out of the model are not occurring (see section III.F.).

We sought comment on the proposed approach to address overlap between CJR and BPCI episodes. The following is a summary of the comments we received and our responses.

*Comment:* Many commenters supported the proposal to apply precedence rules that attribute episodes to BPCI PGPs and PAC providers in cases of overlap with CJR. Commenters noted the significant investment PGPs and PAC providers have made in BPCI and a desire for these entities to continue engagement in care redesign under BPCI. A commenter noted that for many providers, 3-year participation in BPCI will expire near the time when CJR begins requiring participant hospitals to accept full financial responsibility for episode spending. The commenter believes it would not be appropriate to change the episode precedence rules for BPCI providers prior to the conclusion of providers' 3-year BPCI participation, as attributing Model 2 and Model 3 PGP and PAC LEJR episodes to CJR in lieu of BPCI could create confusion. Commenters also requested that CMS provide additional clarification of a number of potential scenarios beyond those addressed in the proposed rule.

Some commenters disagreed with our proposed policy to apply precedence to BPCI Model 2 and Model 3 PGPs and PAC providers. Commenters contended that the proposed policy was unfair, given that BPCI participants entered models voluntarily, but hospitals in CJR were not given the opportunity to opt out and would be at risk for episodes where others did not perceive enough opportunity to voluntarily enter into risk agreements under BPCI. Commenters expressed concern that, given the precedence rules, CJR hospitals could potentially lose many episodes to BPCI and may be financially responsible for a low volume of episodes. Some commenters also suggested we apply a minimum threshold to remove hospitals from the CJR model based on BPCI PGP participation.

A commenter disagreed with the proposal for BPCI PAC entities at risk for a shorter episode duration than the CJR proposed episode to be given precedence. Another commenter cited the potential for patient steering issues that could arise due to our proposed policy to give BPCI PGPs precedence over CJR hospitals for LEJR episodes. In particular, the commenter was concerned that the precedence rules would lead to BPCI PGPs capturing lower-risk episodes, leaving CJR hospitals at risk for more high-risk episodes. The commenter suggested we give precedence to CJR episodes over BPCI PGP and PAC episodes to mitigate steering concerns.

Another commenter was concerned about potential confusion when episodes initiated at the same acute care hospital could be in both models; for example, when episodes initiated by a BPCI PGP at a hospital or discharged to a Model 3 PAC are attributed to BPCI while the remaining episodes are a part of CJR. The commenter believed that following both sets of rules (for the BPCI and CJR models) within the same hospital could be confusing for hospitals and partner providers and suppliers, limiting providers' ability to target care redesign efforts toward patients for whom a CJR hospital is financially responsible. Another commenter requested CMS publish a public list of BPCI episode initiators whose episodes would take precedence over CJR episodes.

*Response:* We agree with commenters' assertion that maintaining participation in the voluntary BPCI models and recognizing the significant investments in care redesign and care coordination already made by BPCI participants is important. BPCI participants have an agreement with CMS and in some cases have already been participating in the voluntary BPCI initiative for several years.

In response to commenters' requests for additional examples of overlap scenarios, we clarify that LEJR overlap could occur in, but is not limited to, the following situations:

- A beneficiary is admitted to a CJR hospital for an LEJR procedure and discharged to a PAC provider participating in BPCI Model 3 for the LEJR episode; the episode is attributed to the BPCI Model 3 PAC provider.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure by a PGP participating in BPCI Model 2; the episode is attributed to the BPCI Model 2 PGP.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure by a PGP participating in BPCI Model 3; the episode is attributed to the BPCI Model 3 PGP.
- A beneficiary is admitted to a CJR hospital for an LEJR procedure, followed by a second phased LEJR procedure within 90 days of the first procedure. The second LEJR procedure is attributed to a PGP participating in BPCI Model 2 or 3 or is followed by admission to a PAC provider participating in BPCI Model 3 for the LEJR episode. The first LEJR episode would be canceled and the second episode would be attributed to the BPCI provider.

We acknowledge that some CJR hospitals could be financially at risk for a small proportion of LEJR episodes initiated at the hospital if there are high-volume PGPs or PAC providers in their community initiating LEJR episodes under BPCI, yet we continue to believe those hospitals have opportunity under the CJR model. Physicians and PAC providers may already have worked on care redesign for LEJR beneficiaries, and the hospitals have an opportunity to learn from that experience. Having a smaller number of beneficiaries in the CJR model to begin with also places hospitals at less financial risk, which may allow them to more rapidly and nimbly design care pathways, test them, and refine them on a smaller number of beneficiaries and with less resources than if all of the hospital's LEJR beneficiaries were in the CJR model from the start. We also note that, given that many providers' 3-year participation in BPCI would end in 2017 or 2018, in many cases full financial responsibility for all of a participant hospital's LEJR procedures under the CJR model would not be in effect until the conclusion of the BPCI participation period when the CJR participant hospitals could have responsibility for a larger number of episodes. By that point in time, CJR participant hospitals should have several years of experience with LEJR episodes focusing on quality and efficiency, and the larger number of beneficiaries can then be integrated into existing pathways.

While we understand the concerns of some commenters that physician and PAC providers participating in BPCI will focus on low-risk beneficiaries, leaving higher-risk beneficiaries to be the participant hospital's responsibility under the CJR model so that the CJR model beneficiaries in a performance year will not resemble those in the baseline period used to set target prices, there are a number of model design features that make this unlikely. First, as discussed in section III.C.4.b.(1) of this final rule, we are stratifying episodes on the basis of a beneficiary's hip fracture

status, a major factor related to higher-cost episodes, so that CJR model participant hospitals will be appropriately paid for higher-risk beneficiaries with hip fractures. Second, we will be monitoring for access to care and delayed care as discussed in section III.F. of this final rule as well as under BPCI, and examining the CJR model for unintended consequences such as adverse selection of patients and inappropriate referral practices in the evaluation as discussed in section IV. of this final rule. Section III.C.12. of this final rule also details our enforcement mechanisms for the CJR model.

We appreciate commenters' contention that allowing for both models to coexist for LEJR episodes within the same acute care hospital may be confusing for providers. However, we believe the importance of continuing PGP and PAC participation in BPCI Models 2 and 3 outweighs this risk, and believe that local providers, in the best interest of Medicare beneficiaries and cost and quality success under the two models, will coordinate and collaborate to respond to their circumstances. We also note that while the BPCI and CJR models differ in various ways, the broad goals of the models are the same: Improving quality of care while reducing spending during the episode. We believe it is reasonable for hospitals, PGPs, and PAC providers to engage in care redesign strategies targeted at LEJR episodes in general, regardless of attribution of an LEJR episode to a particular model. Such overlap within the same hospital may incentivize additional coordination between the entities already engaged in care redesign under BPCI and acute care hospitals that will begin such activities as participants in CJR.

In response to the commenter who requested a list of BPCI episode initiators, we refer readers to the publicly available list of current episode initiators in BPCI on the model Web site at *http://innovation.cms.gov/initiatives/Bundled-Payments/Participating-Health-Care-Facilities/index.html.*

*Final Decision:* After consideration of the public comments received, we are finalizing our proposal, without modification, to apply precedence to BPCI Model 2 and Model 3 PGP and PAC provider LEJR episodes. Specifically, if at any time during a beneficiary's CJR LEJR episode, that beneficiary would also be in a BPCI Model 2 or Model 3 LEJR episode, the beneficiary's CJR episode would either not be initiated or would be canceled such that it would not be included in the participant hospital's CJR reconciliation where actual episode spending is compared to the target price.

*Comment:* Many commenters requested that CMS apply precedence rules in cases of CJR and BPCI non-LEJR overlap. Some commenters requested that BPCI non-LEJR episodes would have precedence in the case of overlap between a BPCI non-LEJR episode and a CJR LEJR episode, while others requested that CJR have precedence. Commenters stated that there was no way to fairly attribute savings between the two models in such scenarios, if CMS allows for overlap between CJR and BPCI non-LEJR episodes as proposed. A commenter stated that it would not be possible to comment on which model should have precedence (CJR or BPCI) due to ambiguity about which model would be more prevalent or expanded in the future; another commenter shared this view, but stated that its opinion on which model should have precedence was dependent upon the specific financial arrangements and waivers finalized for the CJR model.

*Response:* We appreciate the feedback and request for clarification on whether BPCI or CJR episode would have precedence when the same beneficiary could be in a CJR model episode and a BPCI non-LEJR episode for an overlapping period of time. We clarify that we did not propose a calculation to attribute savings between the two models when concurrent episodes occur. We proposed that each model would continue to perform financial reconciliation activities as usual. We also believe such overlap situations will be relatively rare, given that many LEJR procedures are elective and would only be furnished when a physician determines it is clinically appropriate for a beneficiary to undergo a major surgery. We believe a beneficiary undergoing an LEJR procedure in close proximity to an inpatient hospitalization for another condition will be an infrequent occurrence. Applying precedence rules could introduce confusion for providers participating in BPCI for non-LEJR episodes and in the CJR model. For example, if a CJR hospital could retrospectively have an LEJR episode canceled if the beneficiary is readmitted to another hospital and initiates a BPCI episode for a non-LEJR episode such as congestive heart failure, the CJR hospital could be generally unaware of the beneficiary's care pathway.

As we noted in the proposed rule, we believe that where there is overlap between BPCI and CJR LEJR episodes, providers would generally be aware of such situations. For example, BPCI PGPs and PAC providers would be aware that a PGP initiating an LEJR episode at a CJR hospital, or an admission to a PAC facility in BPCI Model 3 would cancel the CJR episode. CJR hospitals could maintain a list of BPCI participants in their area. In contrast, if we allow any BPCI non-LEJR episode to cancel all CJR episodes, CJR hospitals may not be aware of the beneficiary's eventual care pathway. For example, CJR hospitals may be unaware of cases in which the CJR LEJR episode is canceled and the non-LEJR BPCI episode takes precedence because a wide range of BPCI clinical episodes and provider types could cancel the CJR episode during the 90 day post-discharge period.

We expect such cases of overlap to be rare given current BPCI participation and the participant CJR model hospitals. We also reiterate that when such overlap occurs, each model (BPCI and CJR) would continue its normal financial reconciliation processes. When overlap occurs, it is possible that savings achieved during one model could also be counted as savings under the other model. In such cases it could be difficult to determine whether savings achieved during an episode were attributable to care redesign activities under BPCI or CJR. However, allowing for overlap between BPCI non-LEJR and CJR episodes will maximize the testing of episodes under both models and encourage providers under BPCI and CJR to engage in care redesign and coordination activities for all beneficiaries attributed to either model. The following examples illustrate potential situations of overlap:

- A beneficiary is admitted to a CJR hospital for an LEJR procedure and later readmitted to the same or a different CJR hospital for a congestive heart failure episode under BPCI.
- A beneficiary is in a BPCI PGP Model 2 episode for chronic obstructive pulmonary disease at a CJR hospital and has an LEJR procedure at the same or a different CJR hospital during the post-anchor hospital discharge period of the BPCI episode.

In both situations, each model would calculate episode spending and perform financial reconciliation as normal.

*Summary of Final Decisions:* After consideration of the public comments received, we are finalizing our proposal, without modification, to apply precedence to BPCI Model 2 and Model 3 PGP and PAC LEJR episodes. By precedence, we mean that if for any portion of CJR model episode, a beneficiary would also be in a BPCI LEJR episode under Model 2 or Model 3, we will cancel (or never initiate) the CJR episode. We refer readers to III.B.3.

for further discussion of the circumstances under which CJR episodes will be canceled. We are also finalizing the proposal, without modification, to allow for overlap between the period of time in which a beneficiary is in a CJR episode and a BPCI non-LEJR episode.

c. Accounting for CJR Reconciliation Payments and Repayments in Other Models and Programs

Under CJR, we proposed to annually, as applicable, make reconciliation payments to or receive repayments from participating CJR hospitals based on their quality performance and Medicare expenditures, as described in section III.C.6. of the proposed rule. While we proposed that these reconciliation payments or repayments would be handled by MACs, the calculation of these amounts would be done separately before being sent through the usual Medicare claims processing systems. Nevertheless, it is important that other models and programs in which providers are accountable for the total cost of care be able to account for the full Medicare payment, including CJR-related reconciliation payments and repayments as described in section III.C.6. of the proposed rule, for beneficiaries who are also in CJR episodes. Accordingly, it is necessary to have beneficiary-specific information on CJR-related reconciliation payments and repayments available when those models and programs make their financial calculations. Thus, in addition to determining reconciliation payments and repayments for the participant hospitals in the CJR model, we proposed to also calculate beneficiary-specific reconciliation payment or repayment amounts for CJR episodes to allow for those other programs and models, as their reconciliation calculation timeframes permit, to determine the total cost of care for overlapping beneficiaries. We would perform the reconciliation calculations for CJR hospitals and make information about the CJR reconciliation or repayment amounts available to other programs and models, such as the Shared Savings Program and Pioneer ACO as well as non-ACO total cost of care models such as CPCi and OCM that begin reconciliation calculations after CJR. For example, this strategy is currently in place to account for overlaps between beneficiaries assigned or aligned to Pioneer and Shared Savings Program ACOs and BPCI model beneficiaries. Beneficiary-specific reconciliation payment or repayment amounts are loaded into a shared repository for use during each program or model's respective reconciliations. However, we note that we proposed not to make separate payments to, or collect repayments from, participating CJR hospitals for each individual episode, but, instead, to make a single aggregate reconciliation payment or repayment determination for all episodes for a single performance year, as discussed in section III.C.6. of the proposed rule. As described in section III.C.6 of the proposed rule, we proposed to conduct reconciliation based on claims data available 2 months after the end of the performance year and a second calculation based on claims data available 14 months after the end of a performance year to account for claims run-out and potential overlap with other models. The rationale for this proposed reconciliation process was to be able to make payments to, and require repayment from, CJR participant hospitals in a timely manner and to be able to account for overlaps in other models and programs. In addition, the timing of the reconciliation was determined giving consideration to when the other total cost of care programs and models conduct their reconciliations so that when they perform their financial calculations, they will have the information necessary to account for beneficiary-specific payments/repayments made under the CJR model as it is consistent with their policies. We intend to report beneficiary-specific payments and repayment amounts made for the CJR model in the CMS Master Database Management (MDM) System that generally holds payments/repayment amounts made for CMS models and programs. Other total cost of care models and programs can use the information on CJR payment/repayment amounts reported in the Master Database Management System in their financial calculations such as in their baseline or benchmark calculations or reconciliations, to the extent that is consistent with their policies.

We sought comment on our proposed approach to ensuring that the full CJR episode payment for a beneficiary is accounted for when performing financial calculations for other total cost of care and episode-based payment models and programs. The following comments and responses refer to the implications of our proposal to ensure other models are able to account for the full CJR episode payment, including any reconciliation payment or repayment amount. As discussed later in this section, many commenters expressed concern about how this policy would affect ACO financial calculations. Because total cost of care models and programs, including the Shared Savings Program and other ACO models, would include the full CJR episode payment (that is, including any reconciliation or repayment amounts) in their annual financial calculations determining the total spending for a beneficiary, most of the savings achieved during a CJR episode would be attributed to the CJR model. As discussed in section III.C.7.e. of this final rule, in some select cases the savings amount represented by the discount percentage could be attributed to a Shared Savings Program or other ACO model entity.

The following is a summary of comments received and our response.

*Comment:* Commenters did not offer feedback on the implications of the proposed policy on overlap with non-ACO total cost of care models. Commenters generally supported the proposal to attribute episode savings to the CJR model when the CJR hospital is aligned to an ACO as a participant or provider/supplier. However, several commenters expressed concern about the proposed policy, requesting that savings earned during an episode (that is, any reconciliation payments) be fully attributed to the ACO—by not accounting for reconciliation payments in determining Medicare spending for an ACO's assigned beneficiaries—when the ACO and CJR participant hospital are unrelated. These commenters claimed that attributing savings to the ACO in such cases is important for the following reasons: Ensuring ACOs are able to earn savings during a CJR episode in some situations, supporting population-based health models, not penalizing providers already taking on risk, and testing a different method of overlap from the BPCI initiative. Several commenters stated that attributing savings to the CJR episode, regardless of whether the ACO and CJR hospital are related, would make ACOs unable to earn savings during any CJR episode and could erode the Shared Savings Program over the long-term as episode-based payment models grow. A commenter also asserted that the proposed policy could result in increased utilization of LEJR procedures in lieu of less costly clinical interventions.

*Response:* We thank commenters for their feedback and engagement on the issue of how to attribute savings among various models and programs when overlap occurs. We also appreciate commenters' support for the proposal to attribute savings to the CJR episode when the CJR hospital is aligned to the ACO as a participant or provider/supplier.

In response to commenters who requested that we fully attribute savings achieved (represented by reconciliation payments) during CJR episodes to the ACO in cases where a beneficiary is assigned to an ACO and initiates a CJR episode at a hospital that is not aligned to the ACO as a participant or provider/supplier, we decline to diverge from the approach we have taken in other episode payment models because we wish to maintain consistency and because such a change would be unworkable, as we discuss later in this section. There are several ways in which CMS potentially could attribute savings achieved during a CJR episode to the ACO in lieu of the CJR hospital, but after considering them, we have concluded that each option has far-reaching and undesirable implications for the policies and operations of both the CJR model and ACOs. The first option would involve making the ACO to which a beneficiary is assigned the financially responsible entity for the CJR episode so that reconciliation payments or repayments would ultimately be the responsibility of the ACO. To accomplish this, we would need to determine a way to make the reconciliation payment to or request the repayment amount from the unrelated CJR hospital on behalf of the ACO. This would mean that the CJR hospital would need to have a financial arrangement with the unrelated ACO to pay the ACO the reconciliation payment or the ACO would need to pay the CJR hospital if payment is due to Medicare. Under this approach, it would be necessary to conduct a separate reconciliation process for beneficiaries attributed to the unrelated ACO and another reconciliation for all other beneficiaries with CJR episodes. This would disrupt our approach to the financial protections discussed in section III.C.8. of this final rule—that is, stop-loss and stop-gain, which are intended to apply to all of a CJR hospital's episodes, because we would need to apply those thresholds separately to the episodes attributed to the unrelated ACO. We believe this, in turn, would be confusing for participant hospitals. We note that this is distinct from our policy to report beneficiary-specific reconciliation amounts in the MDM, as previously discussed in this section, which would occur after performing the reconciliation calculations and applying the stop-loss and stop-gain thresholds for a given hospital across all of its aggregated episodes.

A second approach would be for all models or programs (CJR and the Shared Savings Program or other ACO) to conduct reconciliation activities for all beneficiaries as normal. The attribution of savings for those CJR beneficiaries assigned to an unrelated ACO could be accounted for through the subsequent reconciliation through the following process. Reconciliation payments could be recouped from CJR participant hospitals and paid to the ACOs in cases where a beneficiary was assigned to an ACO and had a CJR episode at an unrelated CJR hospital. However, we decline to adopt this approach because it would introduce significant uncertainty for CJR participant hospitals and could cause large fluctuations in reconciliation and repayment amounts between the initial reconciliation and subsequent calculation. Additional policies would also need to be adopted in order to ensure the financial reconciliation activities for the CJR model and the Shared Savings Program or shared savings models are able to account for such transactions, including further coordination of reconciliation timelines and policies to account for the subsequent reconciliation calculations. At present, we have not made any proposals for such types of financial arrangements between the initiatives that would allow for such transactions.

A final option would be to cancel (or never initiate) a CJR episode for any beneficiary assigned to an unrelated ACO. Beneficiaries assigned to such ACOs would need to be excluded from CJR financial reconciliation calculations. Implementing such a policy would be challenging, given our plan to conduct CJR reconciliation activities prior to ACO financial reconciliations, in which ACOs finalize their list of assigned beneficiaries. It would not be possible to finalize a list of CJR episodes or beneficiaries until after the ACO models or the Shared Savings Program, as applicable, had completed their financial reconciliations. Additionally, CJR participant hospitals would not know until well after episodes were completed whether the hospital was actually responsible for a particular beneficiary's episode under the CJR model. While we note that in some cases a CJR episode could be canceled for other reasons, such as precedence for a BPCI PGP episode as discussed in III.C.7.b, in such cases we believe that CJR hospitals will generally be aware of the possibility of episode cancelation due to BPCI precedence. For example, a CJR hospital may be aware that any time a given PGP furnishes an LEJR procedure to a Medicare beneficiary in the CJR hospital, that beneficiary will most likely be in a BPCI, not CJR, episode. In contrast, the uncertainty of final ACO assignment lists prior to the CJR reconciliation activities could lead to significant unanticipated changes in episode attribution. In addition, the high volume of potential CJR episodes that would be canceled under this approach could potentially limit the scope of the CJR model test. As discussed in section I.A. of this final rule, CJR is intended to be a robust test of episode payment across many types of hospitals.

Because this approach is generally inconsistent with our proposals for the CJR model, we decline to adopt it. In addition, if CMS were to pursue a policy for attributing CJR model episode savings to an ACO in lieu of to the CJR hospital, the ACO—not the hospital—would become the risk-bearing entity for some beneficiaries (those assigned to the ACO), which is inconsistent with our stated policy in section III.A.2. of this final rule to designate hospitals as financially responsible for all CJR episodes. As discussed in detail in section III.A.2. of this final rule, we believe hospitals are the most appropriate entities to manage the care and financial responsibility for CJR episodes. CJR hospitals could be unaware that beneficiaries are assigned to an ACO, given that their episodes would be canceled or attributed to the ACO only in cases where the CJR hospital is not participating in the ACO.

Given the significant complexity such a change would introduce, and the changes in other CJR model and ACO policies and operations that would be required to implement such a change (such as CJR model reconciliation processes, application of financial protections for hospitals, and financial arrangements), we continue to believe it is most appropriate, consistent with the policies of both the CJR model and the Shared Savings Program and other ACO models, and operationally feasible to attribute savings achieved during a CJR episode (that is, reconciliation payments) to the CJR model in all cases. Doing so also attributes these savings to the episode that is most proximate to the beneficiary's care during an LEJR episode. We refer readers to section III.C.7.e. of this final rule for discussion of the CJR discount percentage and attribution of the savings represented by the discount percentage.

We do not agree that our proposal to attribute savings achieved during CJR episodes via reconciliation payments to the CJR participant instead of the ACO incentivizes overutilization of LEJR procedures, penalizes providers taking on risk, or harms population-based health models. First, as discussed in

section III.F.2. of this final rule, we believe that the usual tools employed by CMS including data analysis, the process of tracking patterns of utilization and trends in the delivery of care, and medical review, a clinical audit process by which we verify that services paid by Medicare were reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act, will help to ensure that LEJR procedures under the CJR model are reasonable and necessary. Second, ACOs will be assured of predictable spending (at the amount of the target price, which would in all cases reflect a discount off total spending that would have occurred absent the CJR model) for care provided during CJR episodes, as opposed to the uncertainty of spending for beneficiaries not included in CJR episodes. Although ACOs may estimate they can achieve more savings for these beneficiaries' episodes than the discount factor reflected in the CJR model target price, higher savings are not certain. ACOs will continue to have savings opportunities for CJR model beneficiaries during the other 9 or so months of the ACO's performance year, as well as for unrelated services throughout the CJR model episode. This also holds true for the BPCI episodes currently in testing, which include 48 surgical and medical episodes, many of them far less frequent and with less predictable costs than the LEJR episodes in the CJR model. Finally, the population health focus of ACOs will continue to be valuable as it is much broader than the CJR model, with great potential for improving the overall health of Medicare beneficiaries and reducing costs. For example, the CJR model begins with admission to the inpatient hospital for the LEJR procedure, yet the underlying clinical condition for beneficiaries undergoing elective THA or TKA is most likely to be long-standing osteoarthritis. Evidence-based conservative management of this condition may delay the THA or TKA or eliminate the need for it altogether, in which case a CJR model episode would never occur. The same concept holds true for all of the episode payment models currently in testing that are focused around an inpatient hospitalization. An ACO's expertise and skill in population health care management may sharply reduce the need for inpatient hospitalization, resulting in substantial direct savings to the ACO and no initiation of an episode under an episode payment model.

Coexistence of episode-based payment models and ACOs may lead to improved care redesign and coordination strategies, and ultimately, improved quality of care for beneficiaries. While episode-based payment models such as the CJR model target care during a relatively short time span, models incorporating the total cost of care over a longer time period such as ACOs focus on population health and strategies to improve care coordination across the entire spectrum of care. In order to achieve the agency's goals of better care, smarter spending, and healthier people, CMS must engage providers in a variety of models and rigorously evaluate the results of such models and programs in order to identify specific care redesign strategies and payment mechanisms that are effective in reaching these goals. An important feature of such testing and evaluation is also understanding how various models or programs work alongside other initiatives. For this reason, we believe it is appropriate for CMS to allow for the coexistence of various initiatives such as episode-based payment models and ACOs. Doing so will provide robust information on the results of each model, including information on how particular payment structures fare across a variety of regions and in markets with varying levels of provider participation in other models.

In addition, we note that although there are important structural differences between initiatives such as CJR and the Shared Savings Program or other ACO models, the underlying goals are the same. Both CJR and the ACO initiatives target improved quality of care and reduced spending during a defined period of time. Over time, provider organizations participating in one or both types of models will continue to find ways to work together to better coordinate care for beneficiaries, improve clinical efficiencies and reduce unnecessary utilization of health care services, and succeed financially under various types of payment models and programs.

Finally, while we appreciate commenters' suggestion that we test a different method for overlap with ACOs than that used for the BPCI initiative, we do not intend to test a different savings attribution method at this time. Both BPCI and the CJR model share the common episode-initiating event of an inpatient hospitalization and, in the case of each of these models as designed, we have concluded that the same savings attribution policy is appropriate. As we develop other episode payment models in the future and consider the potential for expansion of successful episode payment models, we will consider the perspectives offered by the commenters on the CJR model in the design of those models as we develop overlap policies or consider changes to existing policies.

For the reasons previously stated, we are finalizing our proposal to attribute savings achieved (via reconciliation payments) during CJR episodes to CJR participant hospitals. We refer readers to section III.C.7.e. of this final rule for discussion of the attribution of savings for the CJR discount percentage.

*Comment:* A commenter requested that CMS not account for overlap between models by including reconciliation payments or savings amounts from one model in the financial calculations for another model. The commenter asserted that any double counting of savings would be offset by compounded efficiencies and clinical integration.

*Response:* We agree with the commenter that the coexistence of various models and programs is likely to result in compounded efficiencies and clinical integration. However, under all models and programs we believe it is important that Medicare Trust Fund payments made on behalf of beneficiaries be accounted for to the extent feasible and that CMS not pay back savings that should be maintained by the Medicare program. We are finalizing various policies, as outlined elsewhere in this section, to minimize the double payment of savings achieved during CJR episodes and under other models and programs. In addition, we note that under the Shared Savings Program regulations at 425.604(a)(6)(ii), CMS considers all Part A and B expenditures, including payments made under a demonstration or model. Given that CJR reconciliation payments are made from the Trust Funds, and can be attributed to a particular assigned beneficiary, the Shared Savings Program regulations require that such payments be taken into account for the calculation of shared savings or losses.

*Comment:* Several commenters requested that CMS provide CJR hospitals with a list of beneficiaries prospectively aligned to ACOs. Commenters stated that such information would aid participants in both CJR and the model or program.

*Response:* We appreciate the commenters' suggestion. However, providing such a list to CJR participants could potentially lead to patient steering. Because we expect hospitals and other providers and suppliers to engage in care redesign activities under both an ACO model or the Shared Savings Program and the CJR model, it would not be appropriate to create incentives for providers and suppliers to

treat beneficiaries differently based on ACO alignment status.

*Comment:* Numerous commenters requested that CMS allow for Shared Savings Program ACOs or other current or future ACOs participating in risk-bearing ACO models (such as under the Next Generation ACO model) to opt out of the CJR model for beneficiaries aligned to those ACOs. Several commenters suggested allowing Track 2 or Track 3 Shared Savings Program ACOs that had achieved savings in previous performance years to opt out of the CJR model for their aligned beneficiaries.

*Response:* As previously discussed, we believe it is possible and desirable for the multiple CMS programs and models to coexist. We also believe the coexistence of episode-based payment models and total cost of care models such as ACOs can lead to increased efficiencies for both initiatives and additional coordination among providers. As discussed in section III.A. of this final rule, we do not believe it would be appropriate to allow ACOs to opt their aligned hospitals out of the CJR model. Such a policy could significantly diminish the number of participants in the CJR model, eroding our ability to evaluate the CJR model. As discussed in section I.A. of this final rule, CJR is intended to test the effect of episode payment across a variety of hospitals. Significantly limiting the scope of the model by allowing ACOs to opt their hospitals out of participation in CJR would impact our ability to achieve the goals of the model.

*Comment:* A commenter requested that if precedence is not given to Shared Savings Program ACOs for savings arising from CJR episodes initiated at unrelated hospitals, CMS should require CJR hospitals to sign agreements with ACOs in the same MSA to coordinate care for such beneficiaries. The commenter suggested such mandated agreements include specific requirements for the CJR hospital to coordinate a beneficiary's care, such as documented use of clinical practice guidelines and a care plan.

*Response:* Requiring this type of agreement would be inappropriate at this time because it is inconsistent with current CMS policies and practices. While we offer opportunities for providers participating in models such as CJR to enter into financial arrangements with other providers and suppliers and encourage model participants to form clinical partnerships or financial arrangements with other providers and suppliers where appropriate, we do not require specific care coordination agreements or arrangements between entities participating in different CMS models or programs. For further information on our policies regarding agreements and relationships between providers and suppliers coordinating care for beneficiaries under the CJR model, we refer readers to section III.C.10. of this final rule for discussion of financial arrangements under the CJR model.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our policy to make reconciliation and repayment amounts under the CJR model available to other models and programs to include in their financial reconciliation calculations.

This policy is set forth at § 510.305.

d. Accounting for PBPM Payments in the Episode Definition

There are currently five CMS models that pay PBPM payments to providers for new or enhanced services as displayed in Table 17. These PBPM payments vary as to their funding source (Medicare Trust Funds or Innovation Center appropriation), as well as to their payment methodology.

In general, these PBPM payments are for new or enhanced provider or supplier services that share the goal of improving quality of care overall and reducing Medicare expenditures for services that could be avoided through improved care coordination. Some of these PBPM payments may be made for services furnished to a beneficiary that is in another Innovation Center model at the that same time that the beneficiary is in a CJR LEJR episode, but the clinical relationship of services paid by the PBPM payments to the CJR episode will vary. For purposes of CJR, we consider clinically related those services paid by PBPMs that are for the purpose of care coordination and care management of any beneficiary diagnosis or hospital readmission not excluded from the CJR episode definition, as discussed in section III.B.2. of this final rule.

We would determine whether the services paid by PBPM payments are excluded from the CJR episode on a model by model basis based on their funding source and clinical relationship to CJR episodes. If we determine a model's PBPM payments are for new or enhanced services that are clinically related to the CJR episode and the PBPM payment is funded through the Medicare Part A or B Trust Fund, we would include the services paid by the PBPM payment to the extent they otherwise meet the proposed episode definition for the CJR model. That is, we would include the clinically related services paid by a PBPM payment if the services would not otherwise be excluded based on the principal diagnosis code on the claim, as discussed in section III.B.2 of the proposed rule. The PBPM payments for clinically related services would not be excluded from the historical CJR episodes used to calculate target prices when the PBPM payments are present on Part A or Part B claims, and they would not be excluded from calculation of episode actual expenditures during the performance period. PBPM model payments that we determine are clinically unrelated would be excluded, regardless of the funding mechanism or diagnosis codes on claims for those payments. We note that in the case of PBPM model payments, principal diagnosis codes on a Part B claim (which are used to identify exclusions from CJR episodes, as discussed in section III.B. of this final rule), would not denote the only mechanism for exclusion of a service from the CJR episode. All such PBPM model payments we determine are clinically unrelated would be excluded as discussed in this proposal. Finally, all services paid by PBPM payments funded through the Innovation Center's appropriation under section 1115A of the Act would be excluded from CJR episodes, without a specific determination of their clinical relationship to CJR episodes. We believed including such PBPM payments funded under the Innovation Center's appropriation and not included on claims would be operationally burdensome and could significantly delay any reconciliation payments and repayments for the CJR model. In addition, because these services are not paid for from the Medicare Part A or B Trust Fund, we are not confident that they would be covered by Medicare under existing law. Therefore, we believed the services paid by these PBPM payments are most appropriately excluded from CJR episodes. Our proposal for the treatment of services paid through model PBPM payments in CJR episodes would pertain to all existing models with PBPM payments, as well as future models and programs that incorporate PBPM payments. We believed that this proposal is fully consistent with our goal of including all related Part A and Part B services in the CJR episodes, as discussed in section III.B.2. of the proposed rule.

Under this proposal, only one of the active models displayed in Table 17 include services paid by PBPM payments that would not be excluded from CJR episodes. The MAPCP model makes PBPM payments that are funded

through the Trust Fund for new or enhanced services that coordinate care, improve access, and educate patients with chronic illnesses. We expect these new or enhanced services to improve quality and reduce spending for services that may have otherwise occurred, such as hospital readmissions, and consider them to be clinically related to CJR episodes because the PBPM payments would support care coordination for medical diagnoses that are not excluded from CJR episodes. Thus, we proposed that services paid by PBPM payments under the MAPCP model not be excluded from CJR episodes to the extent they otherwise meet the proposed episode definition. While the OCM model will pay for new or enhanced services through PBPM payments funded by the Medicare Part B Trust Fund, we did not believe these services are clinically related to CJR episodes. The OCM model incorporates episode-based payment initiated by chemotherapy treatment, a service generally reported with ICD–9–CM and ICD–10–CM codes that are specifically excluded from the CJR episode definition in section III.B.2. of this final rule. We believed the care coordination and management services paid by OCM PBPM payments would be focused on chemotherapy services and their complications, so the services would be clinically unrelated to CJR episodes. Therefore, we proposed that services paid by PBPM payments under the OCM model be excluded from CJR episodes. Similarly, we proposed to exclude services paid by PBPM payments under the Medicare Care Choices Model (MCCM) from the CJR episode spending calculations. The MCCM focuses on providing care coordination and palliative care services for beneficiaries with certain conditions certified as terminally ill with a life expectancy of 6 months or less that have not elected the Medicare hospice benefit. The MCCM seeks to test whether providing palliative care services, without beneficiaries having to forgo curative care, incentivizes beneficiaries to elect hospice sooner. This is aimed at addressing the large percentage of hospice beneficiaries who elect the hospice benefit too late to fully benefit from the range of services that hospice has to offer at end of life. Since the purpose of the MCCM is to test whether providing palliative care services to beneficiaries who are otherwise eligible to elect the Medicare hospice benefit without requiring the beneficiary to forgo curative care results in beneficiaries electing the hospice benefit sooner, we are not including such payments in the CJR episode spending calculations at this time. In addition, unlike the regular hospice benefits, which are furnished to beneficiaries in lieu of curative care and which therefore can be coordinated during a LEJR episode, as described in section III.B.2.b. of this final rule, the services furnished under the MCCM will be in addition to curative services. We note that we are including such curative services in the episode, as they are consistent with our episode definition described in III.B.2.of this final rule, but not the services represented by the PBPM, which are provided in addition to curative services. Beneficiaries electing the hospice benefit could have lower episode spending because they have forgone curative care, however beneficiaries included in the MCCM may have higher episode spending because they are receiving both curative care and the services represented by the PBPM. We do not want to create incentives that deter providers from enrolling beneficiaries in the MCCM model. We note that Part A and Part B services would be included in episodes in both the historical and performance periods used for spending calculations, while the inclusion of PBPM payments would only occur for those time periods (historical and performance periods) during which the relevant model was active. Given that the MCCM was not active during the CJR initial historical period, if we were to include MCCM PBPM payments they would only be included in CJR performance period spending calculations. Excluding MCCM payments also ensures that we do not incentivize providers to avoid enrolling beneficiaries in the MCCM to minimize the effect of the PBPM payment amounts on episode spending during CJR performance periods.

We acknowledge there may be new models not included in Table 17 that could incorporate a PBPM payment for new or enhanced services. We would plan to make our determination about whether services paid by a new model PBPM payment that is funded under the Medicare Trust Funds are clinically related to CJR episodes through the same subregulatory approach that we are proposing to use to update the episode definition (excluded MS–DRGs and ICD–10–CM diagnosis codes). We would assess each model's PBPM payment to determine if it would be primarily used for care coordination or care management services for excluded clinical conditions under the LEJR episode definition for CJR based on the standards we proposed to use to update the episode definition that are discussed in section III.B.2 of the proposed rule.

If we determine that the PBPM payment would primarily be used to pay for services to manage an excluded clinical condition, we would exclude the PBPM payment from the CJR episode on the basis that it pays for unrelated services. If we determine that the PBPM payment could primarily be used for services to manage an included clinical condition, we would include the PBPM payment in the CJR episode if the diagnosis code on the claim for the PBPM payment was not excluded from the episode, following our usual process for determining excluded claims for Part B services in accordance with the episode definition discussed in section III.C.2 of the proposed rule. We would post our proposed determination about whether the PBPM payment would be included in the episode to the CMS Web site to allow for public input on our planned application of these standards, and then adopt changes to the overlap list with posting to the CMS Web site of the final updated list after our consideration of the public input.

We sought comment on our proposals to account for Innovation Center model PBPM payments under CJR.

The following is a summary of the comments received and our responses.

*Comment:* A commenter supported the proposal to exclude CPCi, OCM, and MCCM PBPM payments and the proposal to seek future public input on PBPM payments that are clinically related to CJR.

*Response:* We thank the commenter for support of our proposal to exclude CPCi, OCM, and MCCM PBPM payments from CJR episode spending calculations.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposed policy, without modification, to include PBPM payments that are funded with Trust Fund dollars, if the services would not otherwise be excluded under the model episode definition. Included PBPM payments would be included in CJR model financial calculations only for historical and performance periods during which the model with a PBPM is active and the PBPM is funded with Trust Fund dollars.

This policy is set forth at § 510.200.

e. Accounting for Overlap With Medicare Initiatives Involving Shared Savings and Total Cost of Care Models

In addition to the Medicare Shared Savings Program under section 1899 of the Act, there are several ACO and other Innovation Center models that make or will make, once implemented, providers

accountable for total cost of care over 6 to 12 months, including the Pioneer ACO Model, Next Generation ACO Model, Comprehensive ESRD Care (CEC) Model, CPCi, OCM, and the MAPCP Demonstration. Some of these are shared savings models (or programs, in the case of the Shared Savings Program), while others do not involve shared savings but still hold participating providers accountable for the total cost of care during a defined episode of care, such as OCM. Note that as discussed in section III.C.7.a. of this final rule, ''total cost of care'' models refer to models in which episodes or performance periods include participant financial responsibility for all Part A and Part B spending, as well as some Part D spending in select cases. Each of these payment models holds providers accountable for the total cost of care over the course of an extended period of time or episode of care by applying various payment methodologies. In the proposed rule, we stated our belief that it is important to simultaneously allow beneficiaries to receive care under broader population-based and other total cost of care models, as well as episode payment models that target a specific episode of care with a shorter duration, such as CJR. Allowing beneficiaries to receive care under both types of models may maximize the potential benefits to the Medicare Trust Funds and participating providers and suppliers, as well as beneficiaries. Beneficiaries stand to benefit from care redesign that leads to improved quality for LEJR episodes of care even while also receiving care under these broader models, while entities that participate in other models and programs that assess total cost of care stand to benefit, at least in part, from the cost savings that accrue under CJR. For example, a beneficiary receiving an LEJR procedure may benefit from a hospital's care coordination efforts with regard to care during the inpatient hospitalization. The same beneficiary may be attributed to a primary care physician affiliated with an ACO who is actively engaged in coordinating care for all of the beneficiary's clinical conditions throughout the entire performance year, beyond the 90-day post-discharge LEJR episode.

We proposed that a beneficiary could be in a CJR episode, as defined in section III.B. of this final rule, by receiving an LEJR procedure at a CJR hospital, and also attributed to a provider participating in a model or program in Table 17. For example, a beneficiary may be attributed to a provider participating in the Pioneer ACO model for an entire performance year, as well as have a CJR episode during the ACO's performance year. Each model incorporates a reconciliation process, where total included spending during the performance period or episode are calculated, as well as any potential savings achieved by the model or program. Given that we proposed to allow for such beneficiary overlap, we stated our belief that it would be important to account for savings under CJR and the other models and programs with potential overlap in order that CMS can apply the respective individual savings-related payment policies of the model or program, without attributing the same savings to more than one model or program. In the proposed rule, we stated our belief that when overlap occurs, it is most appropriate to attribute Medicare savings accrued during the CJR time period (hospitalization plus 90 days post-discharge) to CJR to the extent possible. The CJR episode has a shorter duration and is initiated by a major surgical procedure, requiring an inpatient hospitalization. In contrast, the total cost of care models listed in Table 17 incorporate 6 to 12 month performance periods for participants and, in general, have a broader focus on beneficiary health. Our intention was to ensure that CJR episodes are attributed the full expected savings to Medicare to the extent possible. As such, we proposed the following policies to ensure that other programs and models are able to account for the reconciliation payments paid to CJR hospitals to the extent possible prior to performing their own reconciliation calculations and that, in all appropriate circumstances, the CJR model or the other program or model would make an adjustment for savings achieved under the CJR model and partially paid back through shared savings/performance payments under other initiatives to ensure that the full CJR model savings to Medicare is realized.

We proposed that the total cost of care calculations under non-ACO total cost of care models would be adjusted to the extent feasible to account for beneficiaries that are aligned to participants in the model and whose care is included in CJR in order to ensure that the savings to Medicare achieved under CJR (the discount percentage) are not paid back under these other models through shared savings or other performance-based payment. Thus, the non-ACO total cost of care models would adjust their calculations to ensure the CJR discount percentage is not paid out as savings or other performance-based payment to the other model participants. As previously discussed, we believe that the efficiencies achieved during the CJR episode should be credited to the entity that is closest to that care for the episode of care in terms of time, location, and care management responsibility, rather than the broader entity participating in a total cost of care model that spans a longer duration. We proposed that the non-ACO total cost of care models to which this policy would apply would include CPCi, OCM, and MAPCP. We sought comment on our proposal to account for overlap with those non-ACO total cost of care models and any other current or forthcoming models.

We received no comments on our proposed policy to account for the potential for the discount percentage to be paid out as savings by a non-ACO total cost of care model.

We proposed a different policy for accounting for overlap with Shared Savings Program and other ACO models. We noted that given the operational complexities and requirements of the Shared Savings Program reconciliation process, it would not be feasible for the Shared Savings Program to make an adjustment to account for the discount to Medicare under a CJR episode under existing program rules and processes. Additionally, for programmatic consistency across the Shared Savings Program and other ACO models, given that our ACO models generally are tested for the purpose of informing future potential changes to the Shared Savings Program, in the proposed rule we stated our belief that the ACO model overlap adjustment policy should be aligned with the Shared Savings Program policy. Thus, we proposed that under CJR, we would make an adjustment to the reconciliation amount if available to account for any of the applicable discount for an episode resulting in Medicare savings that is paid back through shared savings under the Shared Savings Program or any other ACO model, but only when a CJR participant hospital also participates in the ACO and the beneficiary in the CJR episode is also assigned to that ACO. This adjustment would be necessary to ensure that the applicable discount under CJR is not reduced because a portion of that discount is accounted for in shared savings to the ACO and thus, indirectly, is paid back to the hospital.

However, we proposed not to make an adjustment under CJR when a beneficiary receives an LEJR procedure at a participant hospital and is assigned

to an ACO in which the hospital is not participating. While this proposal would leave overlap unaccounted for in such situations, we did not believe it would be appropriate to hold responsible for repayment the hospital that managed the beneficiary during the episode through a CJR adjustment, given that the participant hospital may have engaged in care redesign and reduced spending during the CJR episode and may be unaware that the beneficiary is also assigned to an ACO. However, we recognized that as proposed this policy would allow an unrelated ACO full credit for the Medicare savings achieved (via the discount percentage) during the episode. The evaluation of the CJR model, as discussed in section IV. of this final rule, would examine overlap in situations where there is overlap between ACOs and CJR to the extent feasible and the potential effect on Medicare savings.

We note that our proposed policy would entail CJR reclaiming from the participant hospital any discount percentage paid out as shared savings under the Shared Savings Program or ACO models only when the hospital is participating in an ACO as a participant or provider/supplier and the beneficiary is assigned to that ACO, while other total cost of care models such as CPCi would adjust for the discount percentage in their calculations to the extent feasible. While it is operationally feasible for smaller total cost of care models in testing, such as CPCi, to make an adjustment to account for any CJR discount percentage paid out as sharing savings or other performance-based payments, the operational complexities and requirements of the large permanent Medicare ACO program, the Shared Savings Program, make it infeasible for that program to make an adjustment in such cases, and in the proposed rule we stated our belief that other ACO models in testing that share operating principles with the Shared Savings Program should follow the same policies as the Shared Savings Program adjustment for certain overlapping ACO beneficiaries. As the landscape of CMS models and programs changes, we may revisit this policy through future rulemaking.

We sought comment on our proposal for adjustments to account for overlap of the discount percentage between CJR and ACO models or programs.

The following is a summary of the comments received and our responses.

*Comment:* A commenter suggested that the proposal could create a disincentive for health systems to expand participation in ACO initiatives due to the more favorable treatment of non-ACO participating hospitals. The commenter also requested that CMS not recoup the portion of the discount percentage paid out as savings, regardless of whether the CJR hospital is participating in an ACO as a participant or provider/supplier.

*Response:* As discussed in section III.C.7.c. of this final rule, we proposed to make CJR reconciliation and repayment amounts available for other models and programs to include in their financial calculations. As commenters noted, the effect of this proposed policy is that savings achieved during the CJR episode would generally be attributed to the CJR model. This proposed policy does not distinguish between ACO and non-ACO entities. In contrast, this section outlines our proposal to make an adjustment to CJR reconciliation amounts in certain situations when a portion of the CJR discount percentage was paid out as savings to an ACO.

For purposes of limiting the instances in which a portion of the discount percentage is doubly counted as savings, we proposed the following. When a beneficiary has a CJR episode and is also assigned to an ACO, it is possible that a portion of the CJR discount percentage could be paid out as savings through the ACO's financial reconciliation. The reconciliation or repayment amounts shared with other models for incorporation into their financial calculations are based on the episode target price, which does not include the spending amount equal to the discount percentage as the discount represents potential savings to Medicare. We proposed that when overlap occurs between CJR hospitals that are participating in an ACO model or program as a participant or provider/supplier, we would make an adjustment to the reconciliation payment (if available) to account for the portion of the discount that was paid to the ACO as shared savings. For example, through the subsequent reconciliation calculation, described in section III.C.6. of this final rule we would reduce a CJR hospital's reconciliation payment by the dollar amount that would have been saved by CMS under the applicable CJR discount percentage, but was determined to have been paid to the ACO as shared savings. In cases where the CJR hospital is not participating in the Shared Savings Program or an ACO model, we would not make such an adjustment. We believe it is reasonable to minimize the situations in which the CJR discount percentage is double counted as savings. We also believe our policy not to make this adjustment in the case of an unrelated ACO is appropriate, given that the ACO may be unaware of the beneficiary's care pathway or that the beneficiary's LEJR episode is included in the CJR model because the CJR hospital and the ACO are not related. We also note that while making an adjustment to a CJR hospital's reconciliation payment is within the scope of the CJR model, adjusting shared savings amounts for ACO entities would necessitate changes to agreements to the Shared Savings Program and other ACO model agreements and methodologies. For the reasons previously stated, we believe unrelated ACOs should not be required to repay the amount of the CJR discount percentage included in the ACO's financial reconciliation.

We do not believe our proposed policy would create a disincentive for health systems to participate in an ACO. Hospitals that are not participating in the Shared Savings Program or other ACO models are treated the same as those participating in an ACO for purposes of determining attribution of savings during the CJR episode represented by the reconciliation payments, as previously discussed in section III.C.7.c. of this final rule. As discussed in that section, after performing the financial reconciliation calculations for CJR, we will put the reconciliation or repayment amounts, as applicable, in a shared repository for other models or programs to use in their own financial calculations. The reconciliation or repayment amounts would be taken into account as if they were FFS payments made for a covered service furnished to a beneficiary, to the extent that such inclusion of payments is consistent with the other model or program's policies. In applying this policy, we will not make a distinction between hospitals or other providers based on participation in an ACO or other initiative. The reconciliation or repayment amounts will be available for all other models or programs to use in their financial calculations as appropriate. In cases where the other initiative includes the CJR reconciliation or repayment amounts in their financial calculations, the savings achieved during an episode would be attributed to CJR, except in cases where the discount percentage is paid out as savings to another model or program participant, as discussed later in this section. In addition, in cases where some or all of the CJR discount percentage is paid out to an ACO hospital through the ACO's financial reconciliation, making an adjustment to the reconciliation payment where available to account for the discount percentage does not penalize the hospital participating in an ACO. Such

adjustment ensures that the discount percentage is not paid out as savings to the same or a related entity.

*Comment:* A commenter questioned the methodology CMS proposed for accounting for such overlap, requesting that the calculation be pro-rated for the 90-day episode and only include the portion related to CJR model participants.

*Response:* Although our calculations to determine reconciliation or repayment amounts would be done in aggregate across all CJR episodes for a given participants, overlap adjustments and calculations would be done at the beneficiary level. Therefore, we do not believe proration is necessary.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, without modification, to account for overlap with non-ACO total cost of care models and ACO models and programs. In cases where a portion of the CJR discount percentage is paid out as savings to a non-ACO model participant, the other model will make an adjustment to their financial reconciliation calculation to the extent feasible. In the case of such overlap with an entity participating in the Shared Savings Program or an ACO model, the CJR model would require repayment of the portion of the discount percentage paid out as savings through the subsequent reconciliation process, by making an adjustment to the reconciliation amount if available. If a CJR hospital did not earn a reconciliation payment, the adjustment would not be made. That is, we will not increase the amount of a hospital's repayment amount in order to account for the portion of the discount percentage paid out as savings. This adjustment would only be undertaken when the CJR hospital is also aligned to an ACO as a participant or a provider/supplier and the beneficiary in the CJR episode was assigned or aligned to the ACO. We may revisit our approach to accounting for overlap with the Shared Savings Program and ACO models in future rulemaking.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing our proposal, without modification, for non-ACO total cost of care models to adjust their financial reconciliation calculations to the extent feasible to ensure that a portion of the CJR discount is not paid out as savings under that model. We are also finalizing our proposal, without modification, to make an adjustment to a CJR hospital's subsequent reconciliation calculation, when the CJR hospital also participates in the ACO and the beneficiary in the CJR episode is also assigned to that ACO, to account for when a portion of the CJR discount percentage is paid out as shared savings the ACO.

This policy is set forth at § 510.305.

8. Limits or Adjustments to Hospital Financial Responsibility

a. Overview

As discussed in section III.A. of the proposed rule, we proposed designating as the financially responsible providers in CJR all acute care hospitals paid under the IPPS that are located in the selected geographic areas for this test of 90-day post-discharge LEJR episodes, with the exception of some hospitals that we proposed to exclude because of participation in BPCI (Models 1, 2, or 4) for LEJR episodes. We are interested in ensuring a broad test of episode payment for this clinical condition among different types of hospitals, including those who may not otherwise choose to participate in an episode payment model. Many of the participant hospitals would likely be key service providers in their communities for a variety of medical and surgical conditions extending well beyond orthopedic procedures. We want to gain experience with this model before extending it to hospitals in uncommon circumstances. In addition, we acknowledge that hospitals designated for participation in CJR currently vary with respect to their readiness to function under an episode payment model with regard to their organizational and systems capacity and structure, as well as their beneficiary population served. Some hospitals may more quickly be able to demonstrate high quality performance and savings than others, even though we proposed that the episode target prices be based predominantly on the hospital's own historical episode utilization in the early years of CJR.

We also note that providers may be incentivized to excessively reduce or shift utilization outside of the CJR episode, even with the quality requirements discussed in section III.C.5. of the proposed rule. In order to mitigate any excessive repayment responsibility for hospitals or reduction or shifting of care outside the episode, especially beginning in performance year 2 of the model when we proposed to begin to phase in responsibility for repaying Medicare for excess episode spending, we proposed several specific policies that are also referenced in section III.C.6.b. of the proposed rule.

b. Limit on Raw NPRA Contribution to Repayment Amounts and Reconciliation Payments

(1) Limit on Raw NPRA Contribution to Repayment Amounts

When hospital repayment responsibility begins in the second performance year of CJR, under this final rule, hospitals would be required to repay Medicare for episode expenditures that are greater than the applicable target price. As discussed in the section III.C.3.c of the proposed rule regarding our proposed pricing adjustment for high payment episodes, hospitals participating in CJR would not bear financial responsibility for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment. Nevertheless, hospitals would begin to bear repayment responsibility beginning in performance year 2 for those episodes where actual episode expenditures are greater than the target price up to the level of the regional episode ceiling. In aggregate across all episodes, the money owed to Medicare by a hospital for actual episode spending above the applicable target price could be substantial if a hospital's episodes generally had high payments. As an extreme example, if a hospital had all of its episodes paid at two standard deviations above the mean regional episode payment, the hospital would need to repay Medicare a large amount of money, especially if the number of episodes was large.

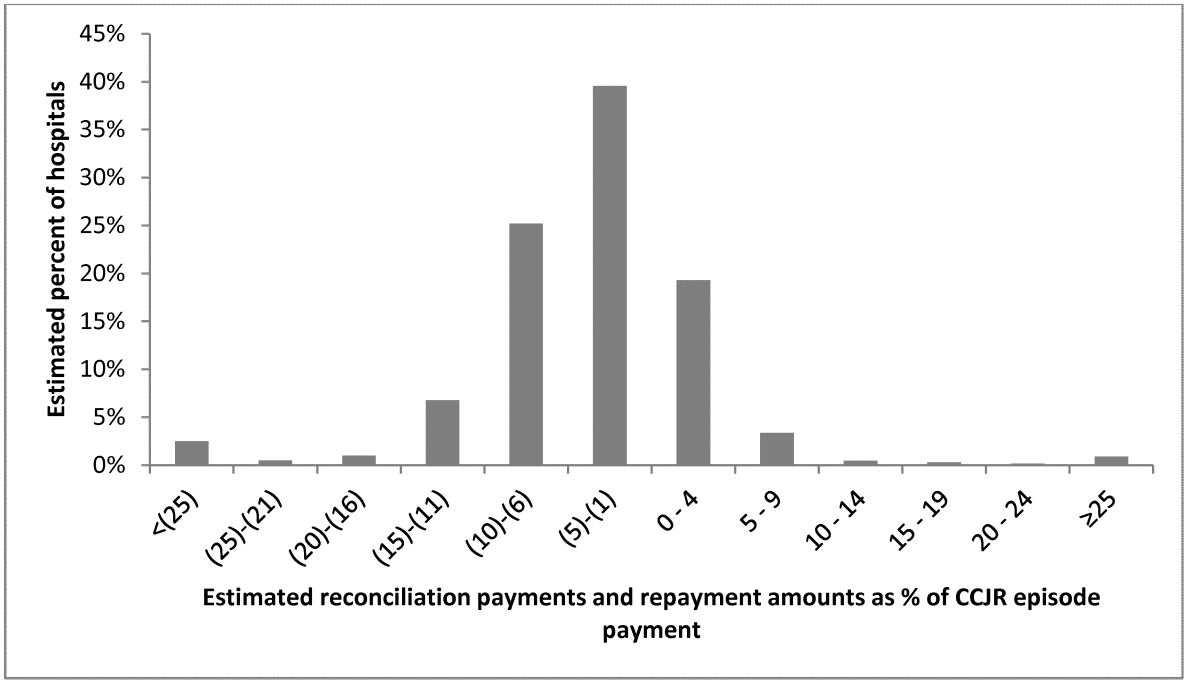
To limit a hospital's overall repayment responsibility for the raw NPRA contribution to the repayment amount under this model, we proposed a 10 percent limit on the raw NPRA contribution to the repayment amount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and subsequent years. Hereinafter we refer to these proposed repayment limits as stop-loss limits. In performance year 2 as we phase in repayment responsibility, the hospital would owe Medicare under the proposed CJR payment model no more than 10 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CJR episodes anchored by that MS–DRG during the performance year, for each anchor MS–DRG in the model. Ten percent provides an even transition with respect to maximum repayment amounts from performance year 1, where the hospital bears no repayment responsibility, to the proposed stop-loss limit in performance years 3 through 5 of 20 percent. In performance years 3

through 5 when repayment responsibility is fully phased in, no more than 20 percent of the hospital's target price for the MS–DRG multiplied by the number of the hospital's CJR episodes with that MS–DRG in that performance year would be owed by the hospital to Medicare under the proposed CJR payment model. The proposed stop-loss percentage of 20 percent would be symmetrical in performance years 3 through 5 with the proposed limit on the raw NPRA contribution to reconciliation payments discussed in the following section.

We had believed that a stop-loss limit of 20 percent is appropriate when the hospital bears full repayment responsibility, based on our assessment of the changes in practice pattern and reductions in quality of care that could lead to significant repayment responsibility under the CJR model, as compared to historical LEJR episode utilization. We estimate that the IPPS payment for the anchor hospitalization makes up approximately 50 percent of the episode target price, and we expect that the anchor hospitalization offers little opportunity for efficiencies to be achieved by reducing Medicare expenditures. In contrast, we expect significant episode efficiencies could be achieved in the 90 days following discharge from the anchor hospitalization through reductions in related hospital readmissions and increased utilization of appropriate lower intensity PAC providers, specifically increased utilization of home health services and outpatient therapy and reduced utilization of SNFs and IRFs. Hospital readmissions and facility-based PAC increase the typical Medicare episode payment by 30 to 45 percent over episodes that do not include these services. The proposed 20 percent stop-loss limit related to the total episode payment corresponds to approximately 40 percent of episode payment for the post-discharge period only, where the major opportunities for efficiency through care redesign occur. Thus, taking into consideration the historical patterns used to set target prices, we believed it is reasonable to hold participant hospitals responsible for repayment of actual episode spending that is up to 20 percent greater than the target price. If a participant hospital's repayment amount due to the raw NPRA would otherwise have exceeded the stop-loss limit of 20 percent (comparable to 40 percent of Medicare payment for the post-discharge period), the hospital's episodes would include much poorer episode efficiency as compared to the hospital's historical episodes, with large proportions of episodes including related readmissions and facility-based PAC, costly services that we do not expect to be necessary for most beneficiaries whose care is well-coordinated and appropriate throughout a high quality LEJR episode.

The following hypothetical example illustrates how the proposed stop-loss percentage would be applied in a given performance year for the episodes of a participant hospital. In performance year 3, a participant hospital had ten episodes triggered by MS–DRG 469, with a target price for these episodes of $50,000. The hospital's episode actual spending for these ten episodes was $650,000. The hospital's raw NPRA that would otherwise be $150,000 ((10 × $50,000) − $650,000) would be capped at the 20 percent stop-loss limit of $100,000 (0.2 × 10 × $50,000) so the hospital would owe CMS $100,000, rather than $150,000. In performance year 3, the same participant hospital also has 100 episodes triggered by MS–DRG 470, with a target price for these episodes of $25,000. The hospital's episode actual spending for these 100 episodes was $2,800,000. The hospital's raw NPRA would be $300,000 ((100 × $25,000) − $2,800,000), an amount that would be due to CMS in full as it would not be subject to the 20 percent stop-loss limit of $500,000 (0.2 × 100 × $25,000).

**FIGURE 4: ESTIMATED DISTRIBUTION OF RECONCILIATION PAYMENTS AND REPAYMENT AMOUNTS UNDER PERFORMANCE YEAR 2 POLICIES, BEFORE CONSIDERATION OF CHANGES IN UTILIZATION, WITHOUT APPLICATION OF STOP-LOSS OR STOP-GAIN LIMITS, BEFORE CONSIDERATION OF QUALITY THRESHOLDS**




Source: Medicare Parts A and B claims, CJR episodes as proposed, between October 1, 2013 and September 30, 2014. Assumes no change in utilization patterns, 2 percent discount factor, 33 percent/66 percent regional and hospital-specific blended target price, and 20 episode threshold for using low historical volume pricing approach. Assumes all participant hospitals with actual episode spending below target prices meet minimum quality thresholds.

As illustrated in Figure 4 where we display results from our national model for the proposed CJR performance year 2 policies when the phase-in of repayment responsibility begins and under the assumption that utilization remains constant, we estimate that the 10 percent stop-loss limit would impact the amount of repayment due to the raw NPRA for about 11 percent of hospitals. For performance year 3, the 20 percent stop-loss limit would affect significantly fewer hospitals, only about 3 percent. We note that the stop-loss limit for years 3 through 5 where repayment responsibility is fully implemented is consistent with the BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-loss limits could actually affect a smaller percentage of hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, any associated repayment amounts due to the raw NPRA. We note that we would include any post-episode spending amount due to Medicare according to the policy proposed in section III.C.8.d. of the proposed rule in assessing the total repayment amount due to the raw NPRA against the stop-loss limit for the performance year to determine a hospital's total payment due to Medicare, if applicable.

We sought comment on our proposal to adopt a 10 percent stop-loss limit in performance year 2 and 20 percent stop-loss limit in performance year 3 and beyond in CJR as hospital repayment responsibility for excess episode spending above the target price is phased in and then maintained in the model. The following is a summary of the comments received and our responses.

*Comment:* Several commenters commented on our proposal for stop-loss limits and expressed support of our proposal to establish stop-loss limits on financial responsibility to 10 percent in year 2, 20 percent in years 3 through 5 that aligned with BPCI and comments in support of the premise of phase-in risk under a mandatory model. However, we also received several comments in opposition of our approach for stop-loss limits. Several commenters requested that we either delay downside risk until Performance Year 3 or set the maximum stop-loss limit at 10 percent, as opposed to 20 percent. Several commenters suggested that we phase in downside risk more slowly with various permutations of the transition to downside risk such as 3 percent in year 3, 6 percent in year 4 and 10 percent in year 5 which aligned more with the Shared Savings Program Track 2 or that we phase in risk with no repayment in year 1 and 2 and stop loss limit set at intervals leading up to 10 percent by performance year 5. Commenters found the stop loss limit to be high considering that the IPPS payment for an LEJR episode comprised 50 percent of a payment, so a 10 percent stop-loss limit would actually represent 20 percent of DRG payment and a 20 percent stop-loss limit would represent 40 percent of DRG payment. Additionally, a commenter was concerned that if hospitals only treat

outlier cases, episode costs could be highly skewed, resulting in repayment. Commenters requested for a more gradual transition to downside risk and a lower stop-loss limit to allow for hospitals to have more time to gain experience under a mandatory model. Additionally, commenters were concerned with the downward pressures faced by hospitals under Medicare reimbursement such as penalties under HRRP, HAC, HITECH and sequestration, and that hospitals need to manage moving to ICD–10 and changes under MACRA. The commenter requested that given the other competing Medicare payment policies that are affecting hospitals, we should provide for a lower stop-loss limit.

*Response:* We thank the commenters for the concerns they raised regarding the proposed stop-loss limit. As described earlier in this final rule, we acknowledge that it may take time for the hospitals to make changes in response to this model and to assume downside risk. We have made several changes in response to such concerns, including delaying the start date of this model to April 1, 2016. Additionally, we have provided safeguards for high cost outlier episodes where we are finalizing capping episodes that are two standard deviations above the mean regional price when determining episode target prices and actual episode payments. Similarly, we agree with commenters that we can provide a more gradual transition to downside risk as hospitals make changes to infrastructure, care coordination, and financial alignment in response to this model. Additionally, we believe a gradual transition to downside risk may reduce the effect of random variation in the early years of the model that could result in highly skewed episode costs that would result in hospital repayment. We are finalizing our policy for no downside risk in Performance Year 1, a stop-loss limit of 5 percent in Performance Year 2, a stop-loss limit of 10 percent in Performance Year 3 and full downside risk with a stop-loss limit of 20 percent in Performance Years 4 and 5. We believe that as we move to regional pricing, hospitals will gain more experience with the model and reduce unnecessary utilization, allowing them better manage additional downside risk capped at 20 percent in Performance Year 4 and 5.

*Comment:* We received a comment that we should align our stop-loss limit policy with BPCI such that we allow hospitals to choose their level of risk among different tracks such as 5 percent stop loss/stop gain, 10 percent stop loss/stop gain or 20 percent stop loss/stop gain limits. The commenter suggested that as hospitals have more control over the risk they take on, they can get more benefit in terms of stop-gain. Commenter suggested that, similar to BPCI, hospitals should be able to change their risk level on a quarterly basis.

*Response:* While this may be similar to how the BPCI model operates, we do not believe it would be appropriate to allow for that option at this time. One of the goals of this model is to evaluate the generalizability of a bundled payment model for selected hospitals and we are interested in evaluating the effects on hospitals for assuming financial responsibility of an episode of care that include downside risk with limits over time. If we allow hospitals to choose their risk level over time, it adds to the operational complexity of this model and may limit the generalizability of the findings.

*Comment:* We received a comment that we should use dollar thresholds to set the stop-loss limits as opposed to percentages. The commenter was concerned that depending on the amount of volume at a hospital, the proposed 10 percent stop-loss limit in Performance Year 2 or 20 percent stop-loss limit in Performance Year 3 through 5 could be difficult to absorb.

*Response:* We believe that it would be operationally complex to establish a stop-loss limit based on a dollar amount given the payment policies finalized in this rule. It would be difficult to establish a dollar amount stop-loss limit as selected hospitals have varying volumes for LEJR episodes that we are not able to predict over the course of the model. Additionally, we are finalizing to adjust target episode prices twice a year in accordance with updates to the Medicare FFS schedules so it would be challenging to additionally adjust stop-loss limits based on a dollar amount. We believe the percentage based stop-loss limits are easier for the public to understand.

*Final Decision:* After consideration of the public comments we received, we are finalizing to apply stop-loss limits of 5 percent in performance year 2, 10 percent in performance year 3 and 20 percent for performance years 4 and 5. This is a change from the proposed rule where we had proposed to apply stop-loss limits of 10 percent in Performance Year 2 and 20 percent in Performance Years 3 through 5. We are codifying these changes at § 510.305(e)(1)(v)(C).

(2) Limit on Raw NPRA Contribution to Reconciliation Payments

We believed a limit on reconciliation payments for CJR would be appropriate for several reasons. Due to the proposed nature of the CJR model during performance year 1, when hospitals have no repayment responsibility for excess episode spending above the target price, CMS bears full financial responsibility for Medicare actual episode payments for an episode that exceed the target price, and we believed our responsibility should have judicious limits. Therefore, we believed it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA as a percentage of episode payment on the basis of responsible stewardship of CMS resources. In addition, we note that beginning in performance year 1, participant hospitals would be eligible for reconciliation payments due to the NPRA if actual episode expenditures are less than the target price, assuming the proposed quality thresholds are met. This proposal for reconciliation payments due to the NPRA provides a financial incentive to participant hospitals from the beginning of the model to manage and coordinate care throughout the episode with a focus on ensuring that beneficiaries receive the lowest intensity, medically appropriate care throughout the episode that results in high quality outcomes. Therefore, we also believed it would be reasonable to cap a hospital's reconciliation payment due to the raw NPRA based on concerns about potential excessive reductions in utilization under the CJR model that could lead to beneficiary harm.

In determining what would constitute an appropriate reconciliation payment limit due to the raw NPRA, we believed it should provide significant opportunity for hospitals to receive reconciliation payments for greater episode efficiency that includes achievement of quality care and actual episode payment reductions below the target price, while avoiding creating significant incentives for sharply reduced utilization that could be harmful to beneficiaries. Thus, for all 5 performance years of the model, we proposed a limit on the raw NPRA contribution to the reconciliation payment of no more than 20 percent of the hospital's target prices for each MS–DRG multiplied by the number of the hospital's episodes for that MS–DRG. Hereinafter we refer to this proposed reconciliation payment limit as the stop-gain limit. This proposed stop-gain limit is parallel to the 20 percent stop-loss limit proposed for performance year 3 and beyond. We believed that a parallel stop-gain and stop-loss limit is important to provide proportionately similar protections to CMS and participant hospitals for their financial

responsibilities under CJR, as well as to protect the health of beneficiaries.

As illustrated in Figure 3 where we displayed results from our national model for the proposed CJR performance year 2 policies under the assumption that utilization remains constant, we estimate that the 20 percent stop-gain limit would impact the reconciliation payment amount due to the raw NPRA of almost no hospitals. We note that a stop-gain limit of 20 percent is consistent with BPCI Model 2 policy. While Figure 3 assumes no change in utilization patterns, under the model test we expect that the proposed stop-gain limit could actually affect a few hospitals in each performance year because we expect LEJR episode care redesign incentivized by the model's financial opportunities to generally reduce unnecessary utilization, thereby reducing actual episode spending and, correspondingly, increasing any associated reconciliation payment amounts due to the raw NPRA. Nevertheless, we believed the proposed stop-gain limit of 20 percent provides substantial opportunity for hospitals to achieve savings over the target price without excessive reductions in utilization, and those savings would be paid back to hospitals fully in most cases without being affected by the stop-gain limit. We sought comment on our proposal to adopt a 20 percent stop-gain limit for all performance years of CJR.

We note that we plan to monitor beneficiary access and utilization of services and the potential contribution of the stop-gain limit to any inappropriate reduction in episode services. We refer readers to section III.F. of the proposed rule for our proposals on monitoring and addressing hospital performance under CJR.

The following is a summary of the comments received and our responses.

*Comment:* Commenters were generally supportive of the proposed stop-gain limit policy at 20 percent as it aligns with BPCI. Another commenter supported the 20 percent stop-gain limit but noted that it is not proportional to the stop-loss limit of 20 percent that was proposed to begin in Performance Year 3 because hospitals have to invest and achieve a minimum 2 percent savings for the Medicare discount from a blend of regional and provider spend which may represent a higher cost savings. Some commenters requested that we remove a stop-gain limit as there are sufficient safeguards in the rule that a stop gain limit was not necessary. Additionally, commenters found a stop-gain limit could serve as a disincentive for hospitals and hospital systems to undertake those reforms that truly transform care.

*Response:* As described earlier, in response to comments that hospitals need a more time to assume downside risk, we are similarly finalizing a more gradual transition the stop-loss limit of 20 percent such that in Performance Year 2, the stop-loss limit is 5 percent, in Performance Year 3, the stop loss limit is 10 percent and in Performance Year 4 and 5, the stop-loss limit is 20 percent. As described in the proposed rule, we proposed parallel stop-loss and stop-gain limits in order to provide proportionately similar protections to CMS and participant for their financial responsibilities under CJR, as well as to protect the health of beneficiaries. Because we are changing our stop-loss limits in this final rule to provide for a more gradual transition to a stop-loss limit of 20 percent, we are believe it would be similarly appropriate to implement a gradual transition to the full stop-gain limit of 20 percent. We believe that the commenters' arguments for requiring additional time to make changes to adapt to the model and to take on financial responsibility similarly applies to hospitals' ability to obtain upside risk under this model. We want to ensure that any repayments in the early years of the model are not due to random variation and accordingly, we have applied a transition to downside risk with more gradual stop-loss limits during the course of the model. We similarly want to ensure that any savings achieved by the hospitals in the early years of the model are also not due to random variation and believe it would be appropriate to apply a parallel transition with more gradual stop-gain limits during the course of the model. Additionally, we want to ensure that changes that the hospitals undertake to improve efficiency that include achievement in quality care and episode payment reductions below the target episode price also do not result in sharp decreases in utilization that could be harmful to beneficiaries. Implementing parallel stop-loss and stop-gain limits provides significant opportunity for hospitals to reduce episode spending through care redesign and care coordination, with appropriate safeguards to ensure that such redesign and coordination activities are clinically appropriate and do not result in reduced quality of care. We recognize that while some hospitals may already be adept at such coordination activities, given that we are requiring participation in the CJR model, such safeguards are necessary to protect beneficiaries and the Trust Funds while hospitals less experienced with care redesign adapt to the model and begin to engage in care redesign activities. While we are implementing various mechanisms to monitor for inappropriate changes in utilization as discussed later in this rule, we believe it would also be appropriate to transition to upside risk in the same manner as we are finalizing to transition to downside risk. In addition, we believe parallel stop-loss and stop-gain limits are appropriate for the CJR model in order to ensure that both CMS and hospitals in the model are similarly at risk for episode spending. Accordingly, we are finalizing a 5 percent stop-gain limit in Performance Year 1 and 2, 10 percent stop-gain limit in Performance Year 3 and 20 percent stop-gain limit in Performance Years 4–5. We believe that it is appropriate that as participant hospitals increase their downside risk, they can similarly increase their opportunity for additional payments under this model.

Additionally, we acknowledge the comment that hospitals need to achieve a certain percent savings, representing the Medicare discount before they are able to receive a reconciliation payment and be subject to the stop-gain limits. As discussed in section III.C.4.b.(9) of this final rule, we are modifying our policy in this final rule so as to use lower discount factors for purposes of determining the hospital's responsibility for excess episode spending not only in performance year 2, but also in performance year 3. Additionally, as discussed in section III.C.5. of this final rule, we are modifying the proposed rule so as to provide different levels of quality incentive payments that would modulate participant hospitals' effective target price discount factor based on their quality performance. We expect participant hospitals to have significant opportunity to improve the quality and efficiency of care furnished during episodes in comparison with historical practice, because this model would facilitate the alignment of financial incentives among providers and suppliers caring for beneficiaries throughout the episode. This discount would serve as Medicare's portion of reduced expenditures from the episode, with any episode expenditure below the target price potentially available as reconciliation payments to the participant hospital where the anchor hospitalization occurred.

*Final Decision:* After consideration of the public comments we received, we are finalizing to establish stop-gain limits that correspond to the finalized stop-loss limits such that the stop-gain limit is 5 percent in Performance Years 1 and 2, 10 percent in Performance Year

3 and 20 percent in Performance Year 4 and 5. We are codifying the establishment of stop-gain limits in this model at § 510.305(e)(1)(v)(D).

c. Policies for Certain Hospitals To Further Limit Repayment Responsibility

As discussed in section III.C.3. of the proposed rule, we proposed that participant hospitals would be subject to repayment responsibility for episode actual spending in excess of the applicable target price beginning in performance year 2. Hospitals participating in CJR would not be responsible for actual episode payments greater than a ceiling set at two standard deviations above the mean regional episode payment as described earlier in this section. Additionally, we proposed a 10 percent limit on the raw NPRA contribution to the repayment amount in performance year 2 and a 20 percent limit on the raw NPRA contribution to the repayment amount in performance year 3 and beyond, as described in the previous section of this final rule.

Though our proposals provide several safeguards to ensure that participant hospitals have limited repayment responsibility due to the raw NPRA, we are proposing additional protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes. Specifically, we are proposing additional protections for rural hospitals, SCHs, Medicare Dependent Hospitals and Rural Referral Centers (RRCs). We note that these categories of hospitals often have special payment protections or additional payment benefits under Medicare because we recognize the importance of preserving Medicare beneficiaries' access to care from these hospitals. In MedPAC's Report to the Congress in June 2012, MedPAC examined issues related to rural Medicare beneficiaries and found that ''The primary objective of rural special payments is to ensure that Medicare does its part to support the financial viability of rural providers that are necessary for beneficiaries' access to care. Some form of special payments will be needed to maintain access in areas with low population density where providers inevitably have low patient volumes and lack economies of scale.'' [44]

We proposed that a rural hospital would have additional protections under the stop-loss limit proposal. For the purpose of this model, we are proposing to define a rural hospital as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103. Such rural hospitals would have additional protections under the stop-loss limit proposal. Consistent with the findings in MedPAC's June 2012 Report to the Congress, we believed rural hospitals may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, particularly if they are the only rural hospital in an area.

Our preliminary analysis examining national spending for MS–DRGs 469 and 470 from October 1, 2013 to September 30, 2014 showed that MS–DRGs 469 and 470 cases represent a slightly higher proportion of cases and spending for rural hospitals than the national average (for example, MS–DRG 470 episode spending represents 12 percent of IPPS spending for rural hospitals and represents 9 percent of IPPS spending nationally).[45] Additionally, our analysis on the distribution of national spending of MS–DRGs 469 and 470 episodes by service type (that is inpatient, outpatient, SNF, Home Health, Physician Part B, DME), found that on average, inpatient services account for the most spending for an MS–DRGs 469 and 470 episode (53 percent of spending for an MS–DRG 469 episode and 55 percent of spending for MS–DRG 470 episode). SNF services account for 27 percent of spending for MS–DRG 469 and 18 percent of spending for MS–DRG 470. The spending distribution for all rural IPPS hospitals also differs from the national average. For rural hospitals, inpatient services for CJR episodes account for more spending than the national average (56 percent for MS–DRG 469 and 57 percent for MS–DRG 470 for rural hospitals) and SNF spending is higher than the national average (29 percent for MS–DRG 469 and 21 percent for MS–DRG 470 for rural hospitals). It is evident that this category of hospitals has different spending patterns than the national average. Furthermore, hospitals in rural areas often face other unique challenges. Rural hospitals may be the only source of healthcare services for beneficiaries living in rural areas, and beneficiaries have limited alternatives should rural hospitals be subject to financial changes under this model. Additionally, because rural hospitals may be in areas with fewer providers including fewer physicians and PAC facilities, rural hospitals may have more limited options in coordinating care and reducing spending while maintain quality of care under this model. We believed that urban hospitals may not have similar concerns as they are often in areas with many other providers and have greater opportunity to develop efficiencies under this model. Given that rural hospitals have different episode spending patterns, have different challenges in coordinating care and reducing cost than urban hospitals and serve as a primary access to care for beneficiaries, we believed that we should have a more protective stop-loss limit policy as described later in this section.

Additionally, we proposed to provide additional protections for SCHs as defined in § 412.92, Medicare Dependent Hospitals as defined in § 412. 108 and RRCs as defined in § 412.96. Hospitals paid under the IPPS can qualify for SCH status if they meet one of the following criteria:

- Located at least 35 miles from other like hospitals.
- Located in a rural area, located between 25 and 35 miles from other like hospitals, and no more than 25 percent of residents or Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital or the hospital has fewer than 50 beds and would meet the 25 percent criterion if not for the fact that some beneficiaries or residents were forced to seek specialized care outside of the service area due to the unavailability of necessary specialty services at the hospital.
- Hospital is rural and located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each of 2 out of 3 years.
- Hospital is rural and the travel time between the hospital and the nearest like hospital is at least 45 minutes.

If an IPPS hospital qualifies to be a SCH, the hospital can be paid the higher of the federal payment rate paid to IPPS hospitals or a cost-based hospital-specific rate as described in § 412.78. Under OPPS, a rural SCH can receive a 7.1 percent add on payment for most services with certain exceptions, in accordance with § 419.43(g). These criteria to qualify for SCH status demonstrate that SCHs are likely to be the sole hospital in an area. Furthermore, additional payments

[44] MedPAC Report to Congress June 2012, Chapter 5, page 121.

[45] Medicare FFS Parts A and B claims, CJR episodes as proposed, between October 1, 2013 and September 30, 2014.

provided under Medicare FFS for SCHs, demonstrates Medicare's interest in ensuring these hospitals are able to provide services to the Medicare beneficiaries who may have limited access to providers in their area. As a result, we believed that we should provide SCHs additional protections from hospital responsibility for repayment in this model. We note that we proposed to exclude these add-on payments for SCHs, as described in section III.C.3.a. of the proposed rule.

MDHs are defined as a hospital that meets the following criteria:

- Located in a rural area.
- Has 100 beds or less.
- Is not a SCH.
- Sixty percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during specified time periods as provided in § 412.108.

MDHs also qualify for special additional payments under the IPPS where an MDH can receive the higher of a payment under the federal standard rate for IPPS hospitals or the payment under federal standard rate for IPPS hospitals plus 75 percent of the difference in payments between a cost based hospital-specific rate and the federal standard rate as described in § 412.108(c). These criteria demonstrate that MDHs are small, rural hospitals that have a high Medicare case mix percentage and receive additional payments under the IPPS to ensure financial stability and preserve beneficiary access to care to these hospitals. Thus, we believed these factors demonstrate that we should provide additional safeguards from hospital responsibility for repayment in order to preserve access to care. We note that we proposed to exclude these payment enhancements for MDHs, as described in section III.C.3.a. of the proposed rule.

RRCs are defined as IPPS hospitals with at least 275 beds that meet the following criteria:

- Fifty percent of the hospital's Medicare patients are referred from other hospitals or from physicians who are not on the staff of the hospital.
- At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital.
- At least 60 percent of all services the hospital furnishes to Medicare patients are furnished to patients who live more than 25 miles from the hospital.

If a hospital does not meet the criteria described previously, a hospital can also qualify for RRC status if a hospital meets the following criteria:

- For specified period of time, the hospital has a case-mix that equals the lower of the median case mix index (CMI) value for all urban hospitals nationally; or the median CMI value for urban hospitals located in its region, excluding those hospitals receiving indirect medical education payments.
- Its number of discharges is at least—

++ 5,000 (or 3,000 for an osteopathic hospital); or

++ The median number of discharges for urban hospitals in the census region in which it is located, set by the CMS through IPPS rulemaking.

- Additionally, a hospital must meet one of the following criteria:

++ More than 50 percent of its active medical staff are specialists who meet the conditions specified at§ 412.96(c)(3).

++ At least 60 percent of all discharges are for inpatients who reside more than 25 miles from the hospital.

++ At least 40 percent of all inpatients treated are referred from other hospitals or from physicians who are not on the hospital's staff.

As an RRC, a hospital can qualify for several additional payments under the IPPS. For example, an RRC is not subject to the 12 percent cap on Medicare Disproportionate Share Hospital payments that a rural hospital would otherwise be subject to, in accordance with § 412.106(d). Although RRCs are larger and have a higher Medicare patient mix, they often serve as the sole provider to treat higher acuity cases, as demonstrated by the RRC qualification criteria. As a result of these unique characteristics of these hospitals, RRCs can receive additional payments under Medicare FFS. Thus, it is also important to provide additional protections for RRCs such that participation in this model does not result in significant financial loss that may reduce access for Medicare beneficiaries.

For these reasons, we proposed a stop-loss limit of 3 percent of episode payments for these categories of hospitals in performance year 2 and a stop-loss limit of 5 percent of episode payments for performance years 3 through 5. More specifically, in performance year 2, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 3 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CJR episodes with that anchor MS–DRG in the performance year. Additionally, in performance years 3 through 5, a rural hospital, SCH, RRC or MDH that is a participant hospital would owe Medicare due to the raw NPRA no more than 5 percent of the hospital's target price for the anchor MS–DRG multiplied by the number of the hospital's CJR episodes with that anchor MS–DRG in the performance year. We believed a different stop-loss limit policy is warranted given the different spending patterns and the unique hospital characteristics for these groups of hospitals as described earlier. We believed this proposal strikes an appropriate balance between protecting hospitals that often serve as the only access of care for Medicare beneficiaries and having these hospitals meaningfully participate in the model. We note that this proposal does not impact the proposed stop-gain policy for these categories of hospitals. Rural hospitals, SCHs, MDHs and RRCs would still have the opportunity to participate in full gains at 20 percent similar to other hospitals.

Hospitals can apply for SCH, MDH and RRC status through their MACs and Regional Office at any time. MACs maintain the list of SCHs, MDHs, and RRCs in the CMS Provider Specific File, which they update on a quarterly basis. The special hospital designations recorded in the Provider Specific File are used in Medicare claims pricing to ensure that these hospitals are paid according to their special hospital designation. Additionally, CMS can identify which hospitals are considered rural for the purpose of this policy, using the Provider Specific File to identify physical geographic location of a hospital and the MACs to identify whether an urban hospital has reclassified to rural under § 412.103 or located in a rural census tract of an MSA defined under § 412.103(a)(1). Thus, we proposed to identify rural hospitals, MDHs, SCHs and RRCs at the time of reconciliation using the Provider Specific File updated in December of the end of the performance year and information from the MACs, and those hospitals would be subject to the 3 percent stop-loss limit policy for that performance year 2, and 5 percent stop-loss limit policy in performance years 3 through 5. For example, to identify the hospitals that would receive a 3 percent stop-loss limit for performance year 2, we would use the Provider Specific File updated in December 2017. We note that the special Medicare payment designation of MDH status has been extended through FY 2017 by legislation under the MACRA. As a result, the proposed additional protections for hospital responsibility for repayment for MDHs would only apply to the extent that MDH status exists under Medicare.

In other words, should MDH expire on or after September 30, 2017, we would not identify hospitals as MDHs to receive the 5-percent stop-loss limit policy for performance year 3. Though MDH status is set to expire after the third quarter of 2017, we would still identify MDHs to receive the 3-percent stop loss limit policy for all of performance year 2.

We note that we also considered excluding rural hospitals, SCHs, MDHs and RRCs from the CJR model altogether due to our concerns of placing significant responsibility for actual episode payment above the target price on these hospitals. Additionally, we were also concerned that from an evaluation perspective, we would not have sufficient sample size of CJR episodes from these categories of hospitals to have significant results of how these groups of hospitals perform under this model. We weighed our reasons for excluding these hospitals with the potential qualitative information we would gain from payment innovation tests on rural hospitals in this model. We concluded that because the CJR model strives to test episode payment for a broad variety of hospitals, it would be preferable to include these hospitals in the CJR model and provide additional protections from a large repayment responsibility. We welcome public comment on our proposed stop-loss limit for rural hospitals, SCHs, MDHs and RRCs and on our alternative consideration to exclude these hospitals entirely from the CJR model.

*Comment:* Several commenters commented on our proposal to provide a more protective stop-loss for rural hospitals, SCHs, MDHs and RRCs. and support of the more protective stop-loss for rural hospitals, SCHs, MDHs and RRCs in order to preserve access to care. Some commenters suggested even more protective stop-loss for these categories of hospitals such as delaying downside risk until Performance Year 3, not providing for downside risk to these hospitals or reducing downside to 1 percent in Performance Year 3, 3 percent in Performance Year Four, and 5 percent in Performance Year Five. We also received comments that we should exclude all-together rural hospitals, SCHs, MDH and RRCs, because as we had acknowledged in the proposed rule, these hospitals may not be able to take on financial risk under this model.

*Response:* We are interested in including these categories of hospitals in our model to see the impact of a bundled payment model in providers that may not otherwise participate in a voluntary program and to better understand the generalizability of this model. However, we recognize the concerns that these categories of hospitals may be less equipped to take on risk and may be the only access of care in their areas. Thus, we proposed to provide for a more limited stop-loss for these categories of hospitals at 3 percent for Performance Year 2 and 5 percent for Performance Years 3 through 5. We had proposed that rural hospitals, MDHs, SCHs and RRCs would still have the opportunity to participate in full gains at 20 percent similar to other hospitals in the model. While we would provide for more limited downside risk for these categories of hospitals for the reasons previously stated, we believe rural hospitals, MDHs, SCHs and RRCs should have the opportunity to receive the gains to the same extent as the other hospitals in the model. We note that we are finalizing to provide for a more gradual stop-loss limit for all other hospitals in the model where the stop-loss limit is 5 percent in Performance Year 2, 10 percent in Performance Year 3 and 20 percent in Performance Years 4–5. Additionally, we are finalizing that the stop-gain limit would be proportional to the stop-loss limit such that in Performance Year 1–2, the stop-gain limit would be 5 percent; in Performance Year 3, the stop-gain limit would be 10 percent; and in Performance Years 4–5, the stop gain limit would be 20 percent We believe the our rationale described earlier in this section to provide for a more gradual transition to stop-gain limits over the course of the model should similarly apply to rural hospitals, SCHs, MDHs and RRCs, particularly in light of our concerns that these categories of hospitals have lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes. We want to ensure that any performance gains by these categories of hospitals are not based on random variation but rather due to implementing changes to achieve efficiencies for high payment episodes. Thus, we are finalizing a more gradual stop-gain limit where the stop-gain limit is 5 percent in Performance Year 2, 10 percent in Performance Year 3 and 20 percent in Performance Years 4–5 for all hospitals in the model, including rural hospitals, SCHs, MDHs and RRCs.

*Comment:* Some commenters recommended that we apply the protective stop-loss limits to other categories of providers with similar low-risk tolerance as rural hospitals, SCHs, MDHs and RRCs. A commenter suggested that we apply the protective stop-loss limit to hospitals in bankruptcy, or undergoing major restructuring under State oversight like safety net hospitals under the Medicaid DSRIP waiver in New York. Another commenter suggested that we provide a protective stop-loss limit for urban referral centers. Another commenter requested that we provide risk corridors for providers that partner with participant hospitals such as IRFs and SNFs.

*Response:* As described in the proposed rule and finalized in this final rule, we are providing additional protections on repayment through more limited stop-loss to certain categories of hospitals that are financially responsible for the 90-day episode spending in this model. Because the provider at risk in this model is the hospital, we believe it is appropriate to provide for limits on financial gain and repayment. We do not believe it would be appropriate to provide risk corridors for other types of providers that may be involved in the continuum of care in a 90 day episode for LEJR such as PAC providers since we will not be making a reconciliation payment or recoupment to those providers. Additionally, we have provided more protective stop-loss limits for certain categories of hospitals that have been recognized by Medicare through additional Medicare FFS payment incentives as often being the only access of care for Medicare beneficiaries and thus it is in our interest to both be able to keep them in the model but recognizing their lower risk tolerance. We do not believe it would be appropriate to provide a limited stop-loss to safety net hospitals under the Medicaid DSRIP waiver in New York. The CJR model addresses a defined population (FFS Medicare beneficiaries undergoing LEJR procedures) for which there are potentially avoidable expenditures (arising from less than optimal care coordination). We believe the DSRIP waiver in New York, which is a waiver provided under the Medicaid program, does not directly impact Medicare FFS payments or a hospital's ability to be in the CJR model at this time. If healthcare transformation initiatives led by States raise concerns about a participant hospital's ability to be in the model, we would address the issue in future rulemaking as necessary. Additionally, we do not believe it would be appropriate to carve out additional protections for other types of hospitals at this time because we want to evaluate, in part, the model's generalizability, which becomes challenging if we add more exceptions. We will continue to monitor the effects

of this model on different categories of hospitals.

*Comment:* We received a comment regarding our proposal to provide MDHs with the more limited stop-loss until the MDH payment status expires under statute in 2017. The commenter requested that we continue to provide the more limited-stop loss for hospitals currently classified as MDHs in the final rule, if MDH status expires. The commenter stated that while the higher payments afforded to MDHs are set to expire in 2017, the concerns on their ability to bear risk and infrastructure capacity issues will remain.

*Response:* We had proposed that hospitals that maintain SCH, MDH or RRC status during the performance year would be subject to the protective stop-loss limit. We understand the concern that with the expiration of MDH status under legislation in September 30, 2017, hospitals will lose their MDH designation and additional Medicare FFS payments provided under the MDH designation. Additionally, under the expiration of MDH status, hospitals would no longer qualify for the protective stop-loss limit tied to that status under this model. Should the MDH payment status expire, some MDHs may apply with their MACs to determine if they qualify as an RRC or SCH and would be able to maintain the protective stop-loss limit in this model. However, we believe it would be inconsistent to apply the additional benefit of protective stop-loss limits to former MDHs when by law, those hospitals are not permitted to retain the other Medicare payment benefits provided to MDHs. Additionally we proposed and are finalizing to identify MDHs at the time of reconciliation in the Provider Specific File updated in December of the end of the performance year and information from the MACs and the MDHs identified in that file would be subject to the protective stop-limits. Should the MDH payment status expire, the Provider Specific File would no longer be updated by MACs to identify hospitals that would have met the expired MDH criteria as it would no longer be a Medicare payment policy. As a result, it would be operationally challenging to appropriately identify the hospitals that would have met the criteria to receive MDH status and to apply protective stop-loss to those hospitals. In general, we recognize that hospitals may change their status on an annual basis during the course of this model based on whether or not a hospital can continue to meet the criteria for the special payment designation, and should a hospital no longer meet the rural, SCH, MDH or RRC designation, it would no longer receive the protective stop-loss limit.

*Comment:* Some comments requested that urban hospitals that reclassify to rural hospitals should be considered rural and be subject to the more protective stop-loss limits. The commenters stated that we generally consider hospitals that undergo urban-to-rural reclassification pursuant to § 412.103 as rural for all Medicare payment purposes and we should consistently treat them as rural under this model and provide this category of hospitals with the more protective stop-loss limit.

*Response:* We agree with the commenters that urban hospitals that reclassify to rural under § 412.103 should be considered a rural hospital for the purposes of this model and receive the more limited stop-loss. We note that we proposed to define rural hospitals as an IPPS hospital that is either located in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103 and to provide a more limited stop-loss for such rural hospitals. However, we note that rural hospitals were inadvertently excluded from the proposed regulation language at § 510.305(e)(1)(v)(E) defining which categories of hospitals would be subject to a lower stop-loss limit. Thus, we are finalizing our proposal to provide a more protective stop-loss limit to rural hospitals as previously defined, as well as MDHs, SCHs and RRC, and will revise the regulatory language at § 510.305(e)(1)(v)(E) to reflect our final policy.

*Comment:* Some commenters were concerned that hospitals with low volume of LEJR episodes have a lower risk tolerance, similar to rural hospitals, SCHs, MDHs and RRCs, may be subject to greater volatility in episode payments and would not have adequate volume to spread the risk of high cost episodes. A commenter's analysis showed that volume is an important determinant of per-episode spending where the average loss was higher for hospitals with fewer episodes. Commenters raised concerns that hospitals with fewer episodes per year may have fewer resources in terms of capital to invest in data infrastructure or care redesign. Commenters suggested that we exclude low volume hospitals from the model, remove downside risk for low volume hospitals or provide a lower stop-loss limit for these hospitals. Commenters provided varying definitions for what qualifies as a low volume hospital ranging from 35 LEJR episodes per year to 100 LEJR episodes per year.

*Response:* We believe that we can address these concerns for low volume hospitals by the other design changes that we are finalizing in this final rule to mitigate risk as participant hospitals implement the necessary changes to improve efficiencies for LEJR episodes and quality of care. These changes made in this final rule would alleviate concerns for low volume hospitals such that special policies for low volume hospitals are not necessary. First, we believe that the policy finalized in this rule in response to public comments to allow for a more gradual transition to the stop-loss limit of 20 percent beginning in Performance Year 4 will alleviate the concerns of hospitals bearing financial risk in a mandatory model. Participant hospitals, including low volume hospitals, will have additional time to make changes in response to the model and gradually take on more upside and downside risk. Second, we believe that our policy, finalized in this rule, to risk stratify MS–DRG 469 and MS–DRG 470 for hip fractures will reduce the variability in the episode costs. We acknowledge that hip fractures can increase the 90 day episode spend so by risk stratifying for hip fracture, we are creating an episode target price for MS–DRG 469 and MS–DRG 470 with and without hip fractures. For a hospital with a lower volume of cases, the risk stratification for hip fractures will mitigate variability in episode costs if a hospital that has fewer episodes treats higher proportion of hip fracture cases. We disagree with commenters that we should exclude low volume hospitals from the model because we are interested in evaluating the experience of small providers and the inclusion of these hospitals in the model is part of our overall desire to see the impact of a bundled payment model in providers who would not otherwise participate in a voluntary program. We would be concerned that setting a threshold for low volume could result in hospital gaming in order to be below that threshold and be excluded from the model.

We are finalizing our proposal to provide for a lower stop-loss limit for rural hospitals, RRCs, MDHs and SCHs and codifying this policy at § 510.305(e)(1)(v)(E). Additionally, we are finalizing to provide a stop-gain limit that correspond to the finalized stop-loss limits for other hospitals in the model such that the stop-gain limit is 5 percent in Performance Years 1 and 2, 10 percent in Performance Year 3 and 20 percent in Performance Years 4 and 5 that would apply to all hospitals in

the model including rural hospitals, MDHs, SCHs and RRCs. We are codifying the establishment of stop-gain limits in this model at § 510.305(e)(1)(v)(D).

d. Hospital Responsibility for Increased Post-Episode Payments

We noted that while the proposed CJR episode would extend 90-days post-discharge from the anchor hospitalization, some hospitals may have an incentive to withhold or delay medically necessary care until after an episode ends to reduce their actual episode payments. We did not believe this would be likely, especially given the relatively long episode duration. However, in order to identify and address such inappropriate shifting of care, we proposed to calculate for each performance year the total Medicare Parts A and B expenditures in the 30-day period following completion of each episode for all services covered under Medicare Parts A and B, regardless of whether the services are included in the proposed episode definition (section III.B. of the proposed rule), as is consistent with BPCI Model 2. Because we base the proposed episode definition on exclusions, identified by MS–DRGs for readmissions and ICD–9–CM diagnosis codes for Part B services as discussed in section III.B. of the proposed rule, and Medicare beneficiaries may typically receive a wide variety of related (and unrelated) services during the CJR episode that extends 90 days following discharge from the anchor hospitalization, there is some potential for hospitals to inappropriately withhold or delay a variety of types of services until the episode concludes, without attending carefully to the episode definition, especially for Part B services where diagnosis coding on claims may be less reliable. This inappropriate shifting could include both those services that are related to the episode (for which the hospital would bear financial responsibility as they would be included in the actual episode spending calculation) and those that are unrelated (which would not be included in the actual episode spending calculation), because a hospital engaged in shifting of medically necessary services outside the episode for potential financial reward may be unlikely to clearly distinguish whether the services were related to the episode or not in the hospital's decisions.

This calculation would include prorated payments for services that extend beyond the episode as discussed in section III.C.3.b. of the proposed rule. Specifically, we would identify whether the average 30-day post-episode spending for a participant hospital in any given performance year is greater than three standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all CJR regional hospitals in the same region as the participant hospital. We proposed that beginning in performance year 2, if the hospital's average post-episode spending exceeds this threshold, the participant hospital would repay Medicare for the amount that exceeds such threshold, subject to the stop-loss limits proposed elsewhere in the proposed rule. We sought comment on this proposal to make participant hospitals responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters opposed the proposal entirely, finding that it represented excessive monitoring of LEJR episodes. Other commenters supported monitoring 30 day post-episode spending, but requested certain modifications to the proposal. Other commenters supported our rationale to monitor a hospital's 30 day post-episode spending to identify potential inappropriate shifting of care, but they opposed our proposal to require participant hospitals to repay Medicare for the amount of post-episode spend that exceeds the threshold. Commenters also requested that the categories of services excluded from the episode definition should also be excluded when determining the 30 day post-episode spending because they found it to be inappropriate to hold a hospital responsible for unrelated services, particularly those related to high-cost conditions like the onset of therapy for cancer or the sudden inclusion of clotting factors for hemophilia. Lastly, we received comments in support of our proposal, agreeing that this approach could help identify participant hospitals that withhold or delay medically necessary care until after an episode ends in order to reduce their actual episode spending. A commenter suggested that rather than requiring a participant hospital to repay Medicare up to the stop-loss limit if they are found to have excessive 30 day post-episode spending, we implement an additional financial penalty for participant hospitals that are found to inappropriately delay care. The commenter suggested that the penalty should not be capped at the proposed stop-loss limit arguing that a hospital that has already substantially exceeded target prices and had to repay CMS under the stop-loss limit will have little incentive to refrain from stinting on care unless a separate penalty exists.

*Response:* We continue to believe that monitoring for 30 day post-episode spending is an appropriate tool to identify inappropriate shifts in care based on our experience with BPCI. We disagree with commenters that we should exclude the same set of services that are excluded from the episode definition in the 30 day post-episode spend because of concern that this model could lead to shifting of both related and unrelated (those not included in the episode definition) services due to some providers encouraging delays of services for beneficiaries that are not immediately necessary, without discriminating between those services that are in and out of the episode definition. Additionally, our experience with BPCI that similarly includes all costs when monitoring for 30 day post-episode spending has helped to inform our policy for the CJR model. Based on our experience with BPCI, we have not found that by including all costs to measure 30 day post-episode spending, that we are inappropriately penalizing hospitals. While we understand commenters' concerns that hospitals could be held responsible for high costs conditions that are not included in the episode definition, our policy aims to strike a balance to hold participating hospitals accountable for inappropriate shifts or delays in care and to provide hospitals with safeguards on financial risk for 30 day post-episode spend. To that end, we are setting a high threshold where only hospitals that have a 30 day post-episode spending average that is three standard deviations above the regional average would be subject to repay that difference to Medicare, and in the case where the hospital's average 30 day post-episode spending exceeds regional average 30 day post-episode spending, the participant hospital would repay Medicare for the amount that exceeds such threshold, subject to the stop loss limits. Additionally, we disagree with the commenter that the penalty for high post-episode spending should not be capped at the proposed stop-loss limit because we still want to provide safeguards for high cost spending for participant hospitals. We note that, as described earlier, we are finalizing to reduce the stop-loss limits for Performance Year 2 and 3 to provide participating hospitals a more gradual transition to assume downside risk

under this model so that repayment under the 30 day post-episode spending policy will be even more limited. We note that participant hospitals that are eligible for reconciliation payments in a performance year that also have an average 30 day post-episode spend that is higher than three standard deviations from the regional average 30 day post-episode spend would have their reconciliation payments reduced by the amount by which spending exceeds three standard deviations.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal as proposed and codifying this policy at § 510.305(e)(1)(v)(A). We note that the term ''CJR eligible hospitals'' is being renamed to ''CJR regional hospitals'' as discussed in response to comments in section III.C.4.b.(4) of this final rule. CJR regional hospitals are all IPPS hospitals located in a region, including IPPS hospitals that are participants in BPCI Model 1 or in the risk bearing period of Models 2 or 4 for LEJR episodes. Accordingly, 30-day post-episode spending for episodes attributed to all IPPS hospitals including BPCI hospitals in the same region as the participant hospital would be included to determine the value that is three standard deviations greater than the regional average 30 day post-episode spend and to determine if a participant hospital has excessive average 30 day post-episode spending.

9. Appeal Procedures

Under the CJR model, we proposed that we would determine target prices for episodes of care using the methodology described in section III.C. of the proposed rule. We proposed to institute a reconciliation payment process as described in section III.C.6. of the proposed rule, and we proposed to retrospectively calculate a participant hospital's actual episode performance relative to its target price after the completion of each performance year. The difference between the actual episode spending of each CJR episode and the target price of that episode (calculated as target price subtracted by CJR actual episode payment) would be aggregated for all episodes initiated at a participant hospital during each performance year. This calculation for a participant hospital would be adjusted for post-episode payment increases and stop gain and stop loss limits, as described in section III.C.6.a. of the proposed rule. We proposed to use quality measure percentiles to determine hospital eligibility to receive the reconciliation payment and use the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment, as described in section III.C.5. of the proposed rule. The NPRA would be reflected in a report sent to the participant hospital called the CJR Reconciliation Report.

We also proposed to institute appeals processes for the CJR model that would allow participant hospitals to appeal matters related to reconciliation and payment (that are previously discussed in this section), as well as non-payment related issues, such as enforcement matters detailed in section III.C.12. of this final rule.

a. Payment Processes

The proposed processes with regard to reconciliation, payment, use of quality measures to determine payment, and stop-loss and stop-gain policies are set forth in detail in sections III.C.5. through 8. of this final rule. In this section, we proposed an appeals process that will apply to the matters addressed in sections III.C.5 through 8. of this final rule, as well as matters not related to payment or reconciliation. These appeals processes will apply to the following payment and reconciliation processes:

- Starting with the CJR Reconciliation Report for performance year 1, if the CJR Reconciliation Report indicates the reconciliation amount is positive, CMS would issue a payment, in a form and manner specified by CMS, for that amount to the awardee within 30 calendar days from the issue date of the CJR Reconciliation Report, unless the participant hospital selects to pursue the calculation error and reconsideration review processes, in which case payment will be delayed as detailed later in this section.
- For performance year 1, if the CJR reconciliation report indicates a repayment amount, the participant hospital would not be required to make payment for that amount to CMS, as we have finalized our proposal not to hold hospitals financially responsible for negative NPRAs for the first performance year. In addition, if it is determined that a CJR hospital has a positive NPRA for performance year 1, and the subsequent calculation for performance year 1 the following year, as described in section III.C.6. of the proposed rule, determines that in aggregate the performance year 1 NPRA and the subsequent calculation amount for performance year 1 is a negative value (adding together the NPRA amount from the reconciliation for performance year 1 as well as the amount determined in the subsequent calculation, which would be detailed on the CJR reconciliation report for performance year 2), the hospital would only be financially responsible for a repayment amount that would net the performance year 1 NPRA and subsequent calculation for performance year 1 to zero. This would be true for performance year 1 only, given our proposal to begin phasing in financial responsibility in year 2 of the model as discussed in section III.C.2.c. of the proposed rule. For performance years 2 through 5 of the model, for example, if there was a positive NPRA for performance year 1 for a given hospital of $3,000, and the subsequent calculation performed in Q2 2018 to account for claims run-out and overlaps determined a repayment amount of $3,500 for claims incurred and overlap during performance year 1, $3,000 would be applied to the CJR reconciliation report for performance year 2. If the positive NPRA for performance year 2 were $5,000, the repayment amount of $3,000 would be netted against the $5,000, and the reconciliation payment for performance year 2 would be $2,000. Given that downside risk has been waived for performance year 1, the remaining $500 would not be added to the CJR reconciliation report for performance year 2. However, beginning with the reconciliation process for performance year 3, any repayment amounts generated through the subsequent calculation process detailed in section III.C.6.b. of this final rule would be netted against any repayment or reconciliation amount on the respective CJR reconciliation reports for performance years 2, 3, 4, and 5. Starting with the reconciliation for performance year 2, if the CJR Reconciliation Report indicates the NPRA is negative, the participant hospital would make payment for the absolute value of that amount to CMS within 30-calendar days from the issue date of the CJR Reconciliation Report, in a form and manner specified by CMS. For example, if there was a positive NPRA for performance year 3 for a given hospital of $1,000, and the subsequent calculation performed in Q2 2019 to account for claims run-out and overlaps determined a repayment amount of $2,500 for claims incurred and overlap during performance year 3, the full $2,500 would be applied to the CJR reconciliation report for performance year 4, subject to the stop loss/stop gain limits detailed in section III.C.8. of this final rule. Thus, if the positive NPRA for performance year 4 were $2,000, the repayment amount of $2,500 would be netted against the $2,000, and a repayment amount for performance year

4 would be $500. Where the participant hospital does not issue payment within 30-calendar days, we will issue a demand letter requiring payment be made immediately.

• The reconciliation or repayment amount may include adjustments, arising from matters from the previous performance year, as necessary to account for subsequent calculations performed for performance years that were specified in earlier CJR Reconciliation Reports, as discussed in section III.C.6. of the proposed rule. For example, we would potentially make determinations of additional monies owed by Medicare to participant hospitals or vice versa in subsequent periods based on the availability of updated Medicare administrative data. These subsequent calculations would be contained in the succeeding reconciliation report. For example, the subsequent calculations applicable to performance year 1 would be contained in the reconciliation report for performance year 2.

• If the participant hospital fails to pay CMS the amount owed by the date indicated in the demand letter, CMS will recoup owed monies from participant hospital's present and future Medicare payments to collect all monies due to CMS. While we proposed that a participant hospital may enter into financial arrangements with CJR collaborators that allow for some risk-sharing, as discussed in section III.C. of the proposed rule, the participant hospital would be solely liable for the repayment of the negative repayment amount to CMS. Where the participant hospital fails to repay CMS in full for all monies owed, CMS would invoke all legal means to collect the debt, including referral of the remaining debt to the United States Department of the Treasury, pursuant to 31 U.S.C. 3711(g).

b. Calculation Error

We proposed the following calculation error process for participant hospitals to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. Participant hospitals would review their CJR reconciliation report and be required to provide written notice of any error, in a notice of calculation error that must be submitted in a form and manner specified by CMS. Unless the participant provides such notice, the reconciliation report would be deemed final within 30 calendar days after it is issued, and CMS would proceed with payment or repayment. If CMS receives a timely notice of an error in the calculation, CMS would respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS would reserve the right to an extension upon written notice to the participant hospital. We proposed that if a participant hospital does not submit timely notice of calculation error in accordance with the timelines and processes specified by CMS, the participant hospital would be precluded from later contesting any of the following matters contained in the CJR reconciliation report for that performance year: Any matter involving the calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; any matter involving the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.

c. Dispute Resolution

(1) Limitations on Review

In accordance with section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

• The selection of models for testing or expansion under section 1115A of the Act.

• The selection of organizations, sites or participants to test those models selected.

• The elements, parameters, scope, and duration of such models for testing or dissemination.

• Determinations regarding budget neutrality under subsection 1115A(b)(3) of the Act.

• The termination or modification of the design and implementation of a model under subsection 1115A(b)(3)(B) of the Act.

• Decisions about expansion of the duration and scope of a model under subsection 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

(2) Matters Subject To Dispute Resolution

We proposed that a participant hospital may appeal an initial determination that is not precluded from administrative or judicial review by requesting reconsideration review by a CMS official. The request for review must be submitted for receipt by CMS within 10 days of the notice of the initial determination, in a form and manner specified by CMS.

(3) Dispute Resolution Process

We proposed the following dispute resolution process. First, we proposed that only a participant hospital may utilize the dispute resolution process. Second, in order to access the dispute resolution process a participant hospital must have timely submitted a notice of calculation error, as previously discussed, for any matters related to payment. We proposed these matters would include any amount or calculation indicated on a CJR reconciliation report, including calculations not specifically reflected on a CJR reconciliation report but which generated figures or amounts reflected on a CJR reconciliation report. The following is a non-exhaustive list of the matters we proposed would need to be first adjudicated by the calculation error process as previously detailed: Calculations of reconciliation or repayment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we proposed could affect reconciliation or repayment amounts. If a participant hospital wants to engage in the dispute resolution process with regard to one of these matters, we proposed it would first need to submit a notice of calculation error. Where the participant hospital does not timely submit a notice of calculation error, we proposed the dispute resolution process would not be available to the participant hospital with regard to those matters for the reconciliation report for that performance year.

If the participant hospital did timely submit a notice of calculation error and the participant hospital is dissatisfied with CMS's response to the participant hospital's notice of calculation error, the hospital would be permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request would be submitted in a form and manner and to an individual or office specified by CMS. The reconsideration review request would provide a detailed explanation of the basis for the dispute and include supporting documentation

for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA or post-episode spending amount in accordance with CJR rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, post-episode spending amount, target prices or any items listed on a reconciliation report.
- The application of quality measures to a reconciliation payment, including the calculation of the percentiles thresholds of quality measure performance to determine eligibility to receive reconciliation payments, or the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.
- Any contestation based on the grounds that CMS or its representative made an error in calculating or recording such amounts.

Where the matter is unrelated to payment, such as termination from the model, the participant hospital need not submit a notice of calculation error. We proposed to require the participant hospital to timely submit a request for reconsideration review, in a form and manner to be determined by CMS. Where such request is timely received, we proposed CMS would process the request as discussed later in this section.

We proposed that the reconsideration review would be an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official would make reasonable efforts to notify the hospital in writing within 15 calendar days of receiving the participant hospital's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for submission of evidence (the ''Scheduling Notice''). The CMS reconsideration official would make reasonable efforts to schedule the review to occur no later than 30 calendar days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) will apply to reviews conducted pursuant to the reconsideration review process for CJR. The CMS reconsideration official would make reasonable efforts to issue a written determination within 30 days of the review. The determination would be final and binding.

We solicited comment on our proposals related to appeals rights under this model. The two-step appeal process for payment matters—(1) Notice of calculation error, and (2) reconsideration review—is used broadly in other CMS models. We sought comment on whether we should develop an alternative appeal process. We are also interested in whether there should be appeal rights for reductions or eliminations of NPRA as a result of enforcement actions, as discussed in section III.C.12. of the proposed rule, and if so, whether the process for such appeals should differ from the processes proposed here.

The following is a summary of the comments received and our responses.

*Comment:* The comments we received on the calculation error process varied widely. Multiple commenters were supportive of the process, including commenters that have experience in BPCI, in which an identical calculation error process is used. A majority of the comments recommended that CMS extend the timeframe for appeals under the calculation error process. Commenters indicated that they appreciated CMS providing details of an appeal procedure, but many suggested that the 30-day timeframe for submission of a notice of calculation error is too short. Some commenters offered proposals for longer periods; specifically, we received separate comments indicating that 45 days, 60 days, or 180 days would be acceptable timeframes. With regard to the proposal to allow for 180 days, multiple commenters noted that this timeframe is similar to the timeframe afforded hospitals to appeal adjustments in the Medicare Cost Report. Multiple commenters also noted that a longer timeframe for notices of calculation error may benefit participant hospitals in providing additional time to identify and understand calculation errors.

*Response:* We appreciate these comments and are sympathetic to the requests from commenters for more time to review reconciliation reports and submit notices of calculation error. We agree with commenters that providing additional time may benefit some participant hospitals in identifying and understanding calculation errors. We are committed to paying participant hospitals accurately and correctly and believe that the calculation error process serves an important function in achieving that goal.

CMS uses the following processes for appeals that we are finalizing in section III.C.9. of this final rule. The procedures for processing and issuing reconciliation payments and repayments require that we submit the payment files for participant hospitals to the payment systems in batches. CMS uses these processes for several reasons. It is administratively more efficient to continue to use MACs to issue payments to all providers and suppliers that furnish services to beneficiaries during a CJR episode, so as not to disrupt the timing of FFS payments that providers and suppliers normally receive. For reconciliation payments and repayments, CMS has developed a process for processing these payments, which is used for other CMS models. This current process is the result of a substantial number of infrastructure changes to payment and recoupment procedures that were made over a period of several years. As a result, we believe it is appropriate to utilize those processes for the CJR model, given that the challenges associated with establishing these processes, as well as the fact that they were created for other CMS models.

The effect of these processes is that the batches are sent at specified intervals. The first batch is sent after the calculation error timeframe closes. The second batch is sent after CMS has responded to the notices of calculation error of participant hospitals and those hospitals choose to not proceed with the dispute resolution process detailed in section III.C.9.b.(3) of this final rule. The final batch is sent after CMS has adjudicated all of the reconsideration reviews for those participant hospitals that selected to utilize the dispute resolution process.

Given these processes, any extension in the timeframe allowed for submission of notices of calculation error delays payment not only to participant hospitals that choose to utilize the calculation error and dispute resolution processes, but even those participant hospitals that choose not to engage in these processes. As such, we believe the need for extending the deadline for submission of notices of calculation error should be balanced with CMS' goal to issue reconciliation payments and repayments promptly, as an extension for these submissions would delay the processing of reconciliation payments for all participant hospitals for a significant period of time. However, we acknowledge the commenters' concerns and the need for participant hospitals to have adequate time to analyze and prepare notices of calculation error.

Therefore, we believe that a longer timeframe for submission of the calculation error form is appropriate for the CJR model, given that CMS is reconciling on an annual basis, as opposed to quarterly for the BPCI initiative. Given that participant hospitals in CJR are likely have a larger subset of data to review on their annual reconciliation reports than their BPCI counterparts who receive quarterly reconciliation reports, we believe it is

prudent for CMS to allow additional time for participant hospitals to review their reconciliation reports for calculation errors. We agree with the commenters who suggested that 45 days would allow sufficient time for participant hospitals to review reconciliation reports, and if they choose, submit notices of calculation error. We believe that 45 days is the appropriate timeframe to allow for this process, as it responds to the requests for more time than our proposal of 30 days, but does not seriously delay payment of reconciliation payments, in the way in which a submission timeframe of 180 days would do. We considered the recommendations for 60 days, but we rejected these recommendations because we note that the calculation error form represents the first step in a two-step appeals process. Where a participant hospital submits a calculation form and is dissatisfied with CMS' response, the dispute resolution option is available to the participant hospital via a reconsideration review request. Upon receipt of a reconsideration review request, the date of such a review would be scheduled by CMS approximately 130 days from the issue date of the reconciliation report. Thus, we believe that the option for reconsideration review, at a much later date, provides participant hospitals with adequate additional time to analyze the date on reconciliation reports, that a 60-day submission deadline for the calculation error form is unnecessary. Finally, we believe that extending this period to 45 days appropriately balances the goal of CMS to process reconciliation payments on a timely basis with the needs of participant hospitals to have adequate time to review their reconciliation reports and submit notices of calculation error.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal with one modification to allow participant hospitals 45 days to submit a calculation error form. We are finalizing our proposal to process and issue reconciliation payments and collect repayments as described in section III.C.6. of this final rule, and to allow for an optional appeals process, as previously described in this section, in which participant hospitals may submit a calculation error form, as well as have an opportunity to engage in dispute resolution.

With regard to the calculation error process, we are finalizing our proposal with one modification. Participant hospitals may submit a calculation error form to contest matters related to payment or reconciliation, of which the following is a non-exhaustive list: The calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment. Upon receipt of its CJR reconciliation report, the participant hospital may choose to submit a calculation error form. The form must be submitted in a form and manner specified by CMS. Unless the participant provides such notice, the reconciliation report will be deemed final within 45 calendar days after it is issued, and CMS will proceed with payment or repayment. If CMS receives a timely notice of an error in the calculation, CMS will respond in writing within 30 calendar days to either confirm or refute the calculation error, although CMS reserves the right to an extension upon written notice to the participant hospital. If a participant hospital does not submit timely notice of calculation error in accordance with the timelines and processes specified by CMS, the participant hospital is precluded from later contesting any of the following matters contained in the CJR reconciliation report for that performance year: any matter involving the calculation of the participant hospital's reconciliation amount or repayment amount as reflected on a CJR reconciliation report; any matter involving the calculation of NPRA; the calculation of the percentiles of quality measure performance to determine eligibility to receive a reconciliation payment; and the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.

With regard to the dispute resolution process, we are finalizing our proposal without modification. In accordance with section 1115A(d) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

- The selection of models for testing or expansion under section 1115A of the Act.
- The selection of organizations, sites or participants to test those models selected.
- The elements, parameters, scope, and duration of such models for testing or dissemination.
- Determinations regarding budget neutrality under subsection 1115A(b)(3) of the Act.
- The termination or modification of the design and implementation of a model under subsection 1115A(b)(3)(B of the Act.
- Decisions about expansion of the duration and scope of a model under subsection 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

We are also finalizing our proposal without modification regarding the matters subject to dispute resolution, and the process CMS will use to adjudicate dispute resolution matters. Thus, a participant hospital may appeal an initial determination that is not precluded from administrative or judicial review by requesting reconsideration review by a CMS official. The request for review must be submitted for receipt by CMS within 10 days of the notice of the initial determination, in a form and manner specified by CMS. Only a participant hospital may utilize the dispute resolution process.

In order to access the dispute resolution process, a participant hospital must timely submit a calculation error form, as previously discussed, for any matters related to payment. These matters include any amount or calculation indicated on a CJR reconciliation report, including calculations not specifically reflected on a CJR reconciliation report but which generated figures or amounts reflected on a CJR reconciliation report. The following is a non-exhaustive list of the matters that we are requiring must be first adjudicated by the calculation error process as previously detailed: Calculations of reconciliation or repayment amounts; calculations of NPRA; and any calculations or percentile distribution involving quality measures that we proposed could affect reconciliation or repayment amounts. If a participant hospital wants to engage in the dispute resolution process with regard to one of these matters, the participant hospital must first submit a calculation error form. Where the participant hospital does not timely submit a calculation error form, the dispute resolution process is not available to the participant hospital with regard to those matters for the reconciliation report for that performance year.

If the participant hospital does timely submit a calculation error form and the participant hospital is dissatisfied with CMS's response to the participant hospital's calculation error form, the hospital is permitted to request reconsideration review by a CMS reconsideration official. The reconsideration review request must be submitted in a form and manner and to

an individual or office specified by CMS. The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA or post-episode spending amount in accordance with CJR rules. The following is a non-exhaustive list of representative payment matters:

- Calculations of NPRA, post-episode spending amount, target prices or any items listed on a reconciliation report.
- The application of quality measures to a reconciliation payment, including the calculation of the percentiles thresholds of quality measure performance to determine eligibility to receive reconciliation payments, or the successful reporting of the voluntary PRO THA/TKA data to adjust the reconciliation payment.
- Any contestation based on the grounds that CMS or its representative made an error in calculating or recording such amounts.

Lastly, we are finalizing our proposal without modification that the reconsideration review is an on-the-record review (a review of briefs and evidence only). The CMS reconsideration official will make reasonable efforts to notify the hospital in writing within 15 calendar days of receiving the participant hospital's reconsideration review request of the date and time of the review, the issues in dispute, the review procedures, and the procedures (including format and deadlines) for submission of evidence (the ''Scheduling Notice''). The CMS reconsideration official will make reasonable efforts to schedule the review to occur no later than 30 calendar days after the date of the Scheduling Notice. The provisions at § 425.804(b), (c), and (e) will apply to reviews conducted pursuant to the reconsideration review process for CJR. The CMS reconsideration official will make reasonable efforts to issue a written determination within 30 days of the review. The determination will be final and binding.

This modification is set forth in § 510.310(a)(1). The remainder of the proposal is finalized as proposed and set forth in § 510.310.

10. Financial Arrangements and Beneficiary Incentives

a. Financial Arrangements

As previously noted, in the proposed rule we stated our belief that given the financial incentives of episode payment in CJR, participant hospitals in the model might want to engage in financial arrangements to share reconciliation payments or hospital internal cost savings or both, as well as responsibility for repaying Medicare, with providers and suppliers making contributions to the hospital's episode performance on spending and quality. Such arrangements would allow the participant hospitals to share all or some of the reconciliation payments they may be eligible to receive from CMS, or the participant hospital's internal cost savings that result from care for beneficiaries during a CJR episode. Likewise, such arrangements could allow the participant hospitals to share the responsibility for the funds needed to repay Medicare with providers and suppliers engaged in caring for CJR beneficiaries, if those providers and suppliers have a role in the hospital's episode spending or quality performance. We use the term ''CJR collaborator'' to refer to such providers and suppliers, who we proposed may include the following:

- SNFs.
- HHAs.
- LTCHs.
- IRFs.
- PGPs.
- Physicians, nonphysician practitioners, and providers or suppliers of therapy services.

We stated our belief that CJR collaborators should have a role in the participant hospital's episode spending or quality performance. Accordingly, we proposed that the CJR collaborator would directly furnish related items or services to a CJR beneficiary during the episode and/or specifically participate in CJR model LEJR episode care redesign activities, such as attending CJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CJR beneficiaries' clinical courses; developing episode analytics; or preparing reports of episode performance under the direction of the participant hospital or a CJR collaborator that directly furnishes related items and services to CJR beneficiaries. We also stated that in addition to playing a role in the participant hospital's episode spending or quality performance, physician, nonphysician, and PGP CJR collaborators must directly furnish services to CJR beneficiaries in order to receive a gainsharing payment as result of their financial arrangement with the participant hospital. We sought comment on our proposed definition of CJR collaborators, as well as our proposed definition of a provider's or supplier's role in the participant hospital's episode spending or quality performance.

We proposed that certain financial arrangements between a participant hospital and a CJR collaborator be termed a ''CJR sharing arrangement,'' and that the terms of each CJR sharing arrangement be set forth in a written agreement between the participant hospital and the CJR collaborator. We proposed to use the term ''Participation Agreement'' to refer to such agreements. We proposed that a ''CJR sharing arrangement'' would be a financial arrangement contained in a Participation Agreement to share only the following: (1) CJR reconciliation payments (as that term is defined in section III.C. of the proposed rule); (2) the participant hospital's internal cost savings (as that term is defined later in this section); and (3) the participant hospital's responsibility for repayment to Medicare, as discussed later in this section. Where a payment from a participant hospital to a CJR collaborator is made pursuant to a CJR sharing arrangement, we proposed to define that payment as a ''gainsharing payment.'' A gainsharing payment may only be only composed of the following: (1) Reconciliation payments; (2) internal cost savings; or (3) both. Where a payment from a CJR collaborator to a participant hospital is made pursuant to a CJR sharing arrangement, we proposed to define that payment as an ''alignment payment.'' We proposed that CJR sharing arrangements that provide for alignment payments would not relieve the participant hospital of its ultimate responsibility for repayment to CMS. Many of the programmatic requirements discussed later in this final rule for gainsharing payments and alignment payments are similar to those in Model 2 of the BPCI initiative.

CJR sharing arrangements must be solely related to the contributions of the CJR collaborators to care redesign that achieve quality and efficiency improvements under this model for CJR beneficiaries. All gainsharing payments or alignment payments between participant hospitals and CJR collaborators resulting from these arrangements must be auditable by HHS, as discussed later in this section, to ensure their financial and programmatic integrity. We emphasized that any CJR collaborator that receives a gainsharing payment or makes an alignment payment must have furnished services included in the episode to CJR beneficiaries. Furthermore, the payment arrangements for gainsharing payments or alignment payments contained in a CJR sharing arrangement must be actually and proportionally related to

the care of beneficiaries in a CJR episode, and the CJR collaborator must be contributing to the care redesign strategies of the participant hospital.

We considered whether CJR collaborators should be termed ''participants'' in this model, or whether the term ''participant'' should refer only to the participant hospitals located in MSAs selected for participation. If CJR collaborators are participants in the model, we proposed that their activities with regard to CJR beneficiaries would be regulated directly by CMS. However, if CJR collaborators are not participants, but rather are participating entities and individuals in the CJR model through signed agreements with participant hospitals, their activities with regard to CJR beneficiaries would be governed by the Participation Agreement between a CJR collaborator and a participant hospital. Given the large number of potential CJR collaborators, the expected varied nature of their respective arrangements with participant hospitals, and the potential administrative burden in reporting information to CMS, we believed the activities of CJR collaborators with regard to CJR beneficiaries would be best managed by participant hospitals. As we discussed earlier in this final rule, one justification for proposing that acute care hospitals be the provider type financially responsible under the CJR model is the position of the hospital with respect to other providers and suppliers, in terms of coordinating care for CJR beneficiaries. Given that position, we proposed that where participant hospitals enter into Participation Agreements that contain CJR sharing arrangements, the participant hospital must also be responsible for ensuring that those providers and suppliers comply with the terms and requirements of the proposed rule. We sought comments on this proposal; specifically, whether CJR collaborators should be termed participants in this model and subject to the applicable requirements, or whether the responsibility for compliance with the model's requirements is better managed by participant hospitals. We were particularly interested in comments that address the advantages and disadvantages of making CJR collaborators participants in the model, and whether there are certain provider or supplier types that CMS should consider including as ''participants'' in the model.

The following discussion outlines our proposed requirements and responsibilities of participant hospitals that engage in such CJR sharing arrangements. In the proposed rule, we stated our belief that these proposed requirements and responsibilities are essential to ensuring that all CJR sharing arrangements are for the sole purpose of aligning the financial incentives of collaborating providers and suppliers with those of the participant hospital toward the CJR model goals of improved LEJR episode care quality and efficiency. We believed that the rationale for and details of these arrangements must be documented and auditable by HHS, with a direct connection to the arrangements and the participant hospital's episode performance. Finally, we believed that the proposed limitations to the arrangements, as described later in this section, are necessary to ensure the integrity of the CJR model by minimizing incentives for problematic behaviors, such as patient steering. We sought comments on all proposed requirements regarding CJR sharing arrangements.

With respect to whether certain entities or individuals should be prevented from participating in the CJR model, either as participant hospitals or CJR collaborators, we considered whether CMS should conduct screening for program integrity purposes. Many CMS models conduct screening during the application process and periodically thereafter. These screenings examine provider and supplier program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. Where a screening reveals that a provider or supplier has a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues, we may remove that provider or supplier from the model. We utilize these screening processes for many CMS models, including the BPCI initiative.

For several reasons, in the proposed rule we stated our belief that this type of screening for participant hospitals would be inapplicable to the CJR model. Most importantly, this model seeks to evaluate the performance in the model of hospitals located in a particular MSA. We believed it is important that all hospitals that meet the criteria for participation in the model be included. Further, in section III.F. of the proposed rule we proposed that CMS would evaluate the quality of care and institute beneficiary protections via a monitoring plan that in ways that would go beyond some of the efforts of previous or existing CMS models. We solicited comments on this proposal, including whether screening of participant hospitals or CJR collaborators might be appropriate or useful in aiding HHS' program integrity efforts and identifying untrustworthy parties or parties with program integrity history problems.

(1) CJR Sharing Arrangement Requirements

We proposed that each CJR sharing arrangement must include and set forth in writing at a minimum—

- A specific methodology and accounting formula for calculating and verifying internal cost savings, if the participant hospital elects to share internal cost savings through gainsharing payments with CJR collaborators. We proposed to define internal cost savings as the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CJR episodes of care. Internal cost savings would not include savings realized by any individual or entity that is not the participant hospital. Each CJR sharing arrangement must include specific methodologies for accruing and calculating internal cost savings of the participant hospital, where the hospital intends to share internal cost savings through a CJR sharing arrangement. The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with Generally Accepted Accounting Principles (GAAP) and Government Auditing Standards (The Yellow Book). The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CJR collaborator or both;
- A description of the methodology and accounting formula for calculating the percentage or dollar amount of a reconciliation payment received from CMS that will be paid as a gainsharing payment from the participant hospital to the CJR collaborator;
- A description of the methodology, frequency or dates of distribution, and accounting formula for distributing and verifying any and all gainsharing payments;
- A description of the arrangement between the participant hospital and the CJR collaborator regarding alignment payments, where the hospital and CJR collaborator agree through a CJR sharing arrangement to share risk for repayment amounts due to CMS, as reflected on a CJR reconciliation report. The description of this arrangement must include safeguards to ensure that such alignment payments are made solely for

purposes related to sharing responsibility for funds needed to repay Medicare in the CJR model. This description should also include a methodology, frequency of payment, and accounting formula for payment and receipt of any and all alignment payments;

• A provision requiring the participant hospital to recoup gainsharing payments paid to CJR collaborators if gainsharing payments were based on the submission of false or fraudulent data;

• Plans regarding care redesign, changes in care coordination or delivery that are applied to the participant hospital or CJR collaborators or both, and any description of how success will be measured;

• Management and staffing information, including type of personnel or contactors that will be primarily responsible for carrying out changes to care under the model;

• The participant hospital must maintain records identifying all CJR collaborators, and the participant hospital's process for determining and verifying the eligibility of CJR collaborators to participate in Medicare; and

• All CJR sharing arrangements must require compliance, from both the participant hospital and the CJR collaborator, with the policies regarding beneficiary notification set forth in section III.F. of the final rule.

With respect to these requirements for Participation Agreements and CJR sharing arrangements, we considered whether we should require participant hospitals and CJR collaborators to periodically report this information to CMS for purposes of enforcement of these proposed regulations. However, we are mindful of the administrative burden in reporting this information as well as the challenges associated with creating a universal collection tool that would account for all the various iterations of financial arrangements into which participant hospitals and CJR collaborators may enter. We sought comment on this proposal as well as whether CMS should require participant hospitals and CJR collaborators to periodically report data such as: Gainsharing payments and/or alignment payments distributed and received; name and identifier (NPI, CCN, TIN) of all CJR collaborators; and any other relevant information related to Participation Agreements and CJR sharing arrangements that would assist HHS with enforcement of these regulations.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(2) Participation Agreement Requirements

We proposed that the Participation Agreement must obligate the parties to comply, and must obligate the CJR collaborator to require any of its employees, contractors or designees to comply, without limitation, with the following requirements:

• Each individual's or entity's participation in the CJR sharing arrangement is voluntary and without penalty for nonparticipation.

• Any gainsharing payments made pursuant to a CJR sharing arrangement must be made only from the participant hospital to the CJR collaborator with whom the participant hospital has signed a Participation Agreement containing a CJR sharing arrangement. Additionally, we proposed to require the following for all CJR sharing arrangements between a participant hospital and a CJR collaborator that is a PGP:

+ Where a gainsharing payment is made to a CJR collaborator that is a PGP, all monies contained in such a gainsharing payment must be shared only with physician or nonphysician practitioners that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the Net Payment Reconciliation Amount (NPRA), as that term is defined in section III.C.6. of this final rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment. We further proposed that each CJR sharing arrangement between a participant hospital and a CJR collaborator that is a PGP must stipulate that the PGP may not retain any portion of a gainsharing payment or distribute, by any method, any portion of a gainsharing payment to physician or nonphysician practitioners who did not furnish a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA or internal cost savings was generated.

• Any alignment payments made pursuant to a CJR sharing arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a Participation Agreement containing a CJR sharing arrangement.

• Each CJR sharing arrangement must require that the CJR collaborator be in compliance with all Medicare provider enrollment requirements at § 424.500 *et seq.,* including having a valid and active TIN or NPI.

• Any internal cost savings or reconciliation payments that the participant hospital seeks to share through CJR sharing arrangements must meet the requirements set forth in the final CJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP. In no event may the participant hospital distribute any amounts pursuant to a CJR sharing arrangement that are not comprised of either internal cost savings or a reconciliation payment, as those terms are defined in this final rule. All amounts determined to be internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. In no case may internal cost savings reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• Any alignment payments that the participant hospital receives through a CJR sharing arrangement must meet the requirements set forth in the final CJR rule (as finalized) and be administered by the participant hospital in accordance with GAAP.

• CJR sharing arrangements must not include any amounts that are not alignment payments or gainsharing payments.

• Further, we proposed that each Participation Agreement—

++ Between the participant hospital and a CJR collaborator must obligate the CJR collaborator to provide the participant hospital and HHS access to the CJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose. Records, information, and data regarding the CJR sharing arrangement must have sufficient detail to verify compliance with all material terms of the CJR sharing arrangement and the terms of the CJR model;

++ Must require the participant hospital and the CJR collaborator to include in their compliance programs specific oversight of their Participation Agreements and compliance with the requirements of the CJR model;

++ If the participant hospital or CJR collaborator does not have a compliance program, each party must create one and incorporate the provisions described in this part in that program;

++ Must require compliance, from both the participant hospital and the CJR collaborator, with the policies regarding beneficiary notification set

forth in section III.F.2. of this final rule; and

++ Must require the board or other governing body of the participant hospital to have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CJR collaborators, its payment of gainsharing payments and receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

• Participation Agreements must require all CJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS or its designees for the purposes of operating the CJR model.

• Each Participation Agreement must require the CJR collaborator to permit site visits from CMS, or one of its designees, for purposes of evaluating the model.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(3) Gainsharing Payment and Alignment Payment Conditions and Restrictions

We proposed the following conditions and restrictions concerning gainsharing payments and alignment payments made pursuant to a CJR sharing arrangement:

• No entity or individual, whether or not a party to a Participation Agreement, may condition the opportunity to give or receive gainsharing payments in CJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• Participant hospitals would not be required to share reconciliation payments, internal cost savings, or responsibility for repayment to CMS with other providers and suppliers. However, where a participant hospital elects to engage in those activities, we proposed that such activities be limited to the provisions prescribed in the proposed rule.

• We proposed that gainsharing payments must be distributed on an annual basis, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in the proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by electronic funds transfer (EFT).

• We proposed that alignment payments from a CJR collaborator to a participant hospital may be made at any interval, and are required to meet the following criteria:

++ Must be clearly identified and comply with all provisions in the proposed rule, as well as all applicable laws, statutes, and rules;

++ Must not be issued, distributed, or paid prior to the calculation by CMS of a reconciliation report reflecting a negative NPRA;

++ Must not be a loan, advance payments, or payments for referrals or other business; and

++ Must be made by EFT.

• We proposed that each CJR sharing arrangement stipulate that any CJR collaborator that is subject to any action involving noncompliance with the provisions of the proposed rule, engaged in fraud or abuse, providing substandard care, or have other integrity problems not be eligible to receive any gainsharing payments related to NPRA generated during the time that coincides with the action involving any of the issues previously listed until the action has been resolved in a forum or manner that constitutes a final determination, either by the state or federal court of last resort, as applicable, or by CMS, HHS, or its designees.

• No entity or individual, whether or not a party to a Participation Agreement, may condition the opportunity to make or receive alignment payments in CJR on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, any CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• In a calendar year, the aggregate amount of the total gainsharing payments distributed by the participant hospital that are derived from a CJR reconciliation payment may not exceed the amount of the reconciliation payment that the participant hospital received from CMS.

• In a calendar year, the aggregate amount of the total alignment payments received by the participant hospital may not exceed 50 percent of the participant hospital's repayment amount due to CMS. If no repayment amount is due, then no alignment payments may be received by the participant hospital.

• We proposed that the participant hospital must retain at least 50 percent of its responsibility for repayment to CMS, pursuant to the repayment amount reflected in each annual reconciliation report, under the CJR model. Given that the participant hospital will be responsible for developing and coordinating care redesign strategies in response to its participation in the CJR model, we believed it is important that the participant hospital retain a significant portion of its responsibility for repayment to CMS. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no greater than $50 in alignment payments, in the aggregate, from its CJR collaborators.

• Further, we proposed that a CJR sharing arrangement must limit the amount a single CJR collaborator may make in alignment payments to a single participant hospital. We proposed that a single CJR collaborator not make an alignment payment to a participant hospital that represents an amount greater than 25 percent of the repayment amount reflected on the participant hospital's annual reconciliation report. For example, upon receipt of a reconciliation report indicating that the participant hospital owes $100 to CMS, the participant hospital would be permitted to receive no more than $25 in an alignment payment from a single entity or individual who is a CJR collaborator of the participant hospital.

• Gainsharing payments and alignment payments must not induce the participant hospital, CJR collaborators, or the employees, contractors, or designees of the participant hospital or CJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary.

• Individual physician and nonphysician practitioners, whether or not a party to a CJR sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Entities furnishing services to beneficiaries during a CJR episode, whether or not a party to a CJR sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

• Gainsharing methodologies for determining gainsharing payments and alignment payments must not directly account for volume or value of referrals, or business otherwise generated, between or among a participant hospital, any CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• Gainsharing payments must be derived solely from reconciliation payments or internal cost savings or both.

• The total amount of gainsharing payments for a calendar year paid to an individual physician or nonphysician practitioner who is a CJR collaborator must not exceed a cap. The cap is 50 percent of the total Medicare approved amounts under the Medicare Physician Fee Schedule (MPFS) for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner. This cap of 50 percent on gainsharing payments to individual physician or nonphysician practitioner is consistent with the same policy for the BPCI initiative. The purpose of this cap is to limit the amount of gainsharing payments an individual practitioner may receive due to his/her provision of services included in the CJR model.

• The total amount of gainsharing payments for a calendar year paid to a PGP that is a CJR collaborator must not exceed a cap. The cap is 50 percent of the sum of the total Medicare approved amounts under the MPFS for services furnished by physician or nonphysician practitioner members of the PGP to the participant hospital's CJR beneficiaries during a CJR episode by those physicians or nonphysician practitioners.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

(4) Documentation and Maintenance of Records

We proposed to require participant hospitals and CJR collaborators to comply with audit and document retention requirements similar to those required by the Medicare Shared Savings Program, BPCI Model 2, and other Innovation Center models. Specifically, with respect to all Participation Agreements and CJR sharing arrangements, the participant hospital and CJR collaborator must:

• Comply with the retention requirements regarding Participation Agreements and CJR sharing arrangements set forth in subsection III.C.10.(a) of this final rule.

• Maintain and give CMS, the Office of Inspector General of the Department of Health and Human Services (OIG), and the Comptroller General or their designee(s) access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality performance measures, billings, and CJR sharing arrangements related to CJR) sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance, as well as the compliance of any CJR collaborator that has a CJR sharing arrangement with the participant hospital, with CJR rules and requirements, the Participation Agreement, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, the determination, distribution, receipt, or recoupment of gainsharing payments or alignment payments.

• Maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital or CJR collaborator at least 30 calendar days before the normal disposition date; or

++ There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CJR collaborator in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

• Notwithstanding any CJR sharing arrangements, the participant hospital must have ultimate responsibility for adhering to and otherwise fully complying with all provisions of the CJR model.

• OIG Authority is not limited or restricted by the provisions of the CJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

• None of the provisions of the CJR model limits or restricts any other government authority permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

We solicited comments about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters requested clarification regarding the application of the fraud and abuse laws to arrangements contemplated by the CJR model.

*Response:* We understand the commenters' interest in the availability of fraud and abuse waivers for the CJR model. However, as indicated in the proposed rule, such waivers would be issued separately by OIG (as to sections 1128A and 1128B of the Act) and CMS (as to section 1877 of the Act). Any fraud and abuse waivers issued in connection with the CJR model will be available at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html* and on OIG's Web site. No waivers of any fraud and abuse authorities are being issued in this final rule.

*Comment:* Some commenters recommended that CMS rename the proposed ''Participation Agreements'' as ''collaborator agreements.'' The justification for this recommendation was that CJR collaborators, unlike the participant hospital, will not have responsibility for managing the compliance of other CJR collaborators with terms of the CJR sharing arrangement, and that it would be, therefore, appropriate to differentiate ''participant hospitals'' from entities or individuals signing a ''Participation Agreement.''

*Response:* We agree that changing the term from Participation Agreement to collaborator agreement is appropriate and may help to eliminate confusion about the type and purpose of such agreements. To avoid confusion, throughout the remainder of this final rule we are substituting the term collaborator agreement in all instances where the term Participation Agreement was used in the proposed rule. All instances in this final rule in which the term Participation Agreement appears have the same meaning as collaborator agreement.

For the same reason, we are also revising the term ''CJR sharing arrangement,'' to ''sharing arrangement.'' Given that a sharing arrangement is contained in a collaborator agreement that has been created solely for the purpose of establishing a financial arrangement between a participant hospital and a CJR collaborator, we believe the inclusion of the acronym CJR in the term for sharing arrangement is unnecessary. Therefore, to avoid confusion, throughout the

remainder of this final rule we are substituting the term sharing arrangement in all instances where the term CJR sharing arrangement was used in the proposed rule. All instances in this final rule in which the term CJR sharing arrangement appears have the same meaning as sharing arrangement.

*Comment:* Many commenters expressed support for CMS' proposal to allow participant hospitals to enter into financial arrangements with other providers and suppliers to share the participant hospital's reconciliation payments or hospital internal cost savings or both, as well as a portion of the participant hospital's responsibility for repayment to Medicare. Some commenters claimed that past and current experience with gainsharing or risk-sharing have yielded positive results for many hospitals, particularly with regard to aligning the financial incentives of various providers and suppliers that furnish services during an episode of care. For example, A commenter noted that a prior program involving gainsharing yielded significant cost reductions to the hospital participants, while maintaining, and in many cases improving, the quality of care. The commenter noted that it had observed through participation in that gainsharing program that it takes time, discipline, and vigilance to change provider behavior, and that gainsharing was one method of attempting to effectuate such change.

Several commenters supported CMS' proposal to define ''CJR collaborators'' to include only certain providers and suppliers, including that CJR collaborators that are physicians, nonphysicians, or PGPs must furnish services to CJR model beneficiaries. Some of these commenters suggested that these particular provider and supplier types, given the nature of the services they furnish to beneficiaries, have increased commitments to clinical responsibility, to sustainable change, and to a long-term investment in the communities in which they operate, as opposed to entities that do not furnish these types of services to beneficiaries.

By contrast, some commenters expressed disappointment that the list of CJR collaborators did not include individuals such as Infectious Disease Specialists, or entities such as accountable care organizations (ACOs), medical device companies, and other third parties, such as the types of convening organizations participating in other CMMI models. Some of the commenters suggested that CMS should expand the list of potential CJR collaborators to include non-provider or non-supplier entities, particularly given that these entities in many cases have a track record of providing Medicare providers and suppliers participating in other models with support services such as care redesign, data analytics, and general program support. A commenter noted that were device manufacturers allowed to be CJR collaborators, those manufacturers might collaborate with health care providers to make a meaningful contribution to the success of the CJR model and the individual initiatives of participant hospitals. Multiple commenters added that entities like ACOs and conveners might provide such services at a reduced cost through economies of scale—as these organizations could spread the expense of developing this infrastructure over many clients. These commenters also noted that some entities that are not providers or suppliers might be willing to assume a high percentage of downside risk, in order to reduce that risk to participant hospitals.

Additionally, a commenter shared its perspective that CMS failed to indicate whether the proposed list of CJR collaborators is exhaustive, and requested clarification as to whether that was the case. Finally, another commenter requested clarification on the status of episodes in which services are furnished by physicians who opt out of Medicare.

*Response:* We have noted the positive feedback from commenters indicating their support for CMS' proposed list of CJR collaborators. We also value the input from other commenters requesting that CMS expand the list of CJR collaborators to include additional entities, some of which may be neither Medicare providers nor suppliers, and the justifications to consider allowing these entities to participate in gainsharing. We want to point out that infectious disease specialists are physicians and, therefore, could potentially be CJR collaborators based on our proposed list. We also are clarifying that with the exception of PGPs that are CJR collaborators (as discussed later in this section), all other CJR collaborators (SNF, HHAs, LTCHs, IRFs, physicians, nonphysician practitioners, and providers or suppliers of outpatient therapy services) must actually furnish a billable service to CJR beneficiaries during CJR episodes in the calendar year in which the savings or loss was created in order to be eligible to receive a gainsharing payment or make an alignment payment.

Although we are open to reconsidering the eligibility of additional entities to be CJR collaborators in the future based on the early implementation experience with the CJR model, at this time we will not adopt a final policy that includes additional entities or individuals beyond those listed as CJR collaborators in the proposed rule. As we stated in section III.A. of the proposed rule, we selected acute care hospitals as the financially responsible entity because we are interested in evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based reimbursement arrangements. We also stated our belief that it is most appropriate to identify a single type of provider to bear financial responsibility for making repayment to CMS under the CJR model; given that hospitals perform a central role in coordinating episode-related care and ensuring smooth transitions for beneficiaries undergoing LEJR procedures, this role factored in our decision to select IPPS hospitals as the financially responsible entity for this model. Given this structure, we believe that limiting the testing of gainsharing relationships to solely those between hospitals and providers and suppliers enrolled in Medicare is most appropriate because we expect enrolled providers and suppliers to be most directly and specifically engaged with the participant hospitals in care redesign and episode care for beneficiaries who have LEJR surgery at the hospital.

We also note that many of the potential reasons that were suggested by commenters for us to consider allowing individuals and entities other than providers and suppliers to be CJR collaborators eligible for gainsharing payments, such as data analytics and general program support, can be achieved outside of the context of gainsharing through other relationships between the participant hospital and those entities. With the exception of PGPs (as discussed in detail later in this section), we continue to believe that any CJR collaborator that receives a gainsharing payment must have furnished a billable service included in the episode to CJR beneficiaries, that the payment arrangements for gainsharing payments must be actually and proportionally related to the care of beneficiaries in a CJR episode, and that the CJR collaborator must be contributing to the care redesign strategies of the participant hospital. We further note that we operate many models concurrently, and not all providers and suppliers are eligible for participation in all models. Models have

different design features and, therefore, the permitted financial arrangements under the models vary. Testing different financial arrangements in various models provides additional information about important factors in success of models in improving care quality and reducing costs.

Given our experience to date with the intersection between Medicare ACO programs, Medicare ACO models, and bundled payment models, we believe it important to note that financial arrangements between non-Medicare providers and suppliers, such as ACOs or other third parties, are allowed under existing laws, rules, and regulations, outside of the context of the CJR model. While we agree that the potential for leveraging the economies of scale of services offered by many entities that are not Medicare providers or suppliers may be significant, we do not believe their involvement necessitates CMS allowing for gainsharing relationships between hospitals and these entities at this time. In many circumstances, financial arrangements between hospitals and these entities may be possible outside the context of gainsharing under a sharing arrangement in the CJR model. For example, a hospital may pay an ACO for care coordination services the ACO provides during or after a beneficiary's stay in the hospital, in the event that a hospital and the ACO are collaborating and agree to that arrangement. In the event an ACO provides care coordination services to the hospital, the hospital is not precluded from compensating the ACO for the services. In other words, if an ACO hires a case manager to work in the hospital to focus on beneficiaries in CJR episodes, the hospital may contract with the ACO for those case manager services. However, this payment would be outside of the context of the CJR model and would not fall under the categories of a gainsharing payment or alignment payment, as those terms are defined in this final rule. Further, nothing in this section alters the applicable laws, rules, and regulations that apply to such arrangements. Thus, we are maintaining the conditions set forth in the proposed rule, and finalizing the list of CJR collaborators as proposed. This finalized list of CJR collaborators is an exhaustive list—only entities and individuals that meet the criteria listed in this final rule may be eligible as CJR collaborators.

Finally, with regard to the comment regarding physicians that have opted out of Medicare, we note that as discussed in section III.C.3. of this final rule, there are implications related to reconciliation payment when services are furnished by physicians and nonphysician practitioners that have opted out of Medicare. With regard to sharing arrangements, we are clarifying in this final rule that in order to be a CJR collaborator, an individual must not have opted out of Medicare, meaning that the individual physician or nonphysician practitioner must be either enrolled in Medicare as a ''Participating physician/supplier'' or as a ''Non-participating physician/supplier.'' In this model, the payments to physicians and nonphysician practitioners that have opted out of Medicare are not included in a participant hospital's target price and the actual episode spending calculations. Thus, the purpose of this policy is to prevent an individual from receiving a gainsharing payment in the CJR model if he/she has opted out of Medicare.

*Comment:* Some commenters expressed concern that a participant hospital may steer beneficiaries to certain providers and suppliers, particularly PAC providers, with which the participant has a sharing arrangement. Another commenter opined that sharing arrangements have the potential to result in decisions that are not in the best interest of patient care but rather are in the best interest of increased profit for CJR collaborators. The commenter suggested that this incentive-based arrangement may lead to lower quality of care and restricted access to medically necessary services. Several commenters requested that CMS allow hospitals to steer patients to particular providers and suppliers.

*Response:* We emphasize that beneficiaries included in a CJR episode retain their full rights to choose their providers and suppliers. Participant hospitals, providers, and suppliers are reminded that patient steering is not permissible and such entities and individuals must continue to comply with current laws. Participant hospitals and CJR collaborators that engage in sharing arrangements may not adversely impede those rights of the beneficiary. Furthermore, we reiterate that sharing arrangements or gainsharing payments must not induce the participant hospital, CJR collaborators, or the employees, contractors, or designees of the participant hospital or CJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary, and that individual physician and nonphysician practitioners, whether or not a party to a sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments. For further discussion on this topic, we refer readers to see the provisions addressing beneficiary notification in section III.F. of this final rule.

*Comment:* A commenter suggested that hospitals located in rural communities may be less likely to have resources to enter into sharing arrangements with CJR collaborators. The commenter stated that in regions where there is not a core group of PAC providers where patients will seek care, rural hospitals may incur additional costs to try to form arrangements with CJR collaborators to support efforts to reduce costs and improve the quality of care.

*Response:* We appreciate the perspective of the commenter that highlights some of the challenges for providers and suppliers located in rural areas. This model seeks to test episode payment for LEJR procedures initiated at acute care hospitals located in selected Metropolitan Statistical Areas (MSAs). By selecting MSAs as the geographic unit, the majority of participant hospitals located in the selected regions will not be located in rural areas. However, some participant hospitals are located in rural areas, and we agree that these hospitals may face unique challenges in establishing sharing arrangements with CJR collaborators if there are few eligible providers or suppliers, or such providers or suppliers are located across significant distances.

Several studies have shown that Medicare beneficiaries located in rural areas historically have had identifiable patterns pertaining to hospital choice, with results across multiple studies and decades indicating that rural Medicare beneficiaries tend to choose larger hospitals and those offering a broader scope of services.[46] Particularly, patients with complex acute medical conditions have been found to be more likely to bypass their closest rural hospitals for larger, urban hospitals. These patterns have been chronicled across several decades, and we expect that rural hospitals are familiar with many of these studies, as well as related studies demonstrating that patients are more likely to seek care from broader regional networks—comprised of individual rural hospitals—than alternatives with fewer hospitals.[47]

[46] Buczko, W. ''Bypassing of Local Hospitals by Rural Medicare Beneficiaries.'' *Journal of Rural Health.* 1994; 10(4): 237–46.

[47] Tai, Porell, and Adams. ''Hospital Choice of Rural Medicare Beneficiaries: Patient, Hospital Attributes, and the Patient-Physician Relationship.'' *Health Services Research.* 2004; 39(6 Pt 1): 1903–1922.

Perhaps based in part on this research, a number of rural health alliances and rural health networks have been created to address these patient preferences, and we expect these alliances and networks may be useful to rural hospitals in exploring the potential for establishing sharing arrangements with CJR collaborators.

We anticipate that CJR beneficiaries located in rural areas are likely to follow this historical trend, and that some patients will seek care from nonrural hospitals. By contrast, other CJR beneficiaries will initiate CJR episodes at rural hospitals. But this trend is unlikely to be unique to CJR beneficiaries, and we expect that rural hospitals already have established relationships, either on their own or through rural health networks, with providers and suppliers that can furnish services to the hospital's patients upon discharge. Thus, we believe it is possible that rural hospitals may identify a small core group of PAC providers where their model beneficiaries commonly seek care following surgery. We will be providing claims data to assist hospitals in identifying potential CJR collaborators, as discussed in section III.E. of this final rule. Finally, one of the purposes of requiring participation in this model of all hospitals in the selected MSAs is to gain information about the challenges and successes achieved by different types of hospitals in the CJR model, and to share strategies related to success.

*Comment:* Multiple commenters requested that CMS clarify the relationships between participant hospitals and CJR collaborators. A commenter requested that CMS explain whether these are financial or clinical relationships. Another commenter expressed concern that CJR collaborators that are non-compliant with the requirements of this final rule and/or the terms of a collaborator agreement with a participant hospital might make a participant hospital liable or financially responsible for the conduct of other organizations. The commenter reasoned that it would be unreasonable for a participant hospital to be held responsible for the behavior of CJR collaborators with whom they may enter into a contract for the provision of services under this model.

*Response:* With respect to the question of whether arrangements between a CJR collaborator and a participant hospital constitute clinical or financial relationships, we note that a CJR collaborator is a specific type of provider or supplier, as previously described, which has signed a written collaborator agreement with a participant hospital. The collaborator agreement must describe a sharing arrangement between the parties. A sharing arrangement, by definition, documents a financial arrangement between the CJR collaborator and the participant hospital that is for the purpose of making gainsharing payments or alignment payments or both. While a collaborator agreement may also address clinical matters, such as care redesign strategies, a provider or supplier is not a CJR collaborator unless the collaborator agreement signed by the provider or supplier contains a sharing arrangement.

As to the second question of provider responsibility, we proposed that participant hospitals in the CJR model that enter into sharing arrangements ''be responsible for ensuring that those providers and suppliers comply with the terms and requirements of this proposed rule.'' We are not suggesting that CJR collaborators be able to escape responsibility for noncompliance with the Medicare Conditions of Participation, or a state or federal law, rule, or regulation merely by entering into a sharing arrangement. Rather, this provision is meant to not only make participant hospitals aware of their responsibility to oversee their CJR collaborators for compliance with the CJR model, but also to inform the participant hospitals of the potential remedial actions that may be taken against them if their CJR collaborators do not comply with all requirements of the CJR model. Specifically, where CMS, HHS, or its designees discovers an instance of noncompliance by a CJR collaborator with the requirements of the CJR model, CMS, HHS, or its designees may take remedial action against the participant hospital, which may include requiring the participant hospital to terminate a collaborator agreement with a CJR collaborator and prohibit further engagement in the CJR model by that CJR collaborator. Furthermore, this provision requires participant hospitals to include in their collaborator agreements provisions requiring compliance from CJR collaborators with the requirements of the CJR model. This provision is discussed further in section III.C.12. of this final rule, in which we detail the enforcement mechanisms that CMS, HHS, or its designees may apply to a participant hospital.

*Comment:* Several commenters recommended that CMS screen participant hospitals and CJR collaborators to address program integrity concerns.

*Response:* We appreciate the recommendations of the commenters that we screen participant hospitals and CJR collaborators. However, for several reasons, we continue to believe that this type of screening for participant hospitals would be inapplicable to the CJR model. Most importantly, this model seeks to evaluate the performance in the model of hospitals located in a particular MSA. Given this important objective, we believe it is crucial for evaluation purposes that all hospitals that meet the criteria for participation in the model be included. Further, as discussed in sections III.F and IV, we have finalized our proposal to include evaluation and monitoring provisions that go beyond some of the efforts of previous or existing CMS models.

With regard to screening CJR collaborators, we believe the additional administrative burden on participant hospitals and CMS to periodically prepare, collect, and specifically screen lists of CJR collaborators would not substantially enhance the program integrity protections otherwise built into the model design. We note that CMS will be monitoring for inappropriate behavior of participant hospitals through monitoring efforts specifically for this model. We further note that CMS retains all of its existing mechanisms to directly monitor providers and suppliers, even if they are CJR collaborators. We have included a number of enforcement mechanisms in this final rule that will be available to CMS should a participant hospital or CJR collaborator be out of compliance with the model's requirements.

*Comment:* Some commenters recommended that CMS provide additional opportunities for entities and individuals other than participant hospitals to assume downside risk under the model. Several commenters indicated that the risk sharing arrangements CMS proposed, via alignment payments from CJR collaborators to participant hospitals, are too limited. In particular, commenters called for PGPs to be able to take on increased risk beyond the 25 percent of a participant hospital's repayment amount that CMS proposed. These commenters suggested that if PGPs were permitted to negotiate sharing arrangements containing provisions for higher gainsharing payments, they would be able to assume greater financial risk as well. Commenters further suggested that transferring risk to PGPs in this manner would be unlikely to result in problematic behaviors such as patient steering, but rather, that such allowances would result in greater provider alignment and better patient care.

*Response:* We believe the limits proposed on alignment payments perform two important functions. First, as described in section III.A. of this final rule, we seek to test in this model the effects of placing financial responsibility on acute care hospitals for episodes of care initiating with an inpatient stay involving LEJR procedures. While we agree with the commenters that some ability to share downside risk could be useful for participant hospitals and CJR collaborators in creating greater provider alignment and improving patient care, we believe that allowing a participant hospital to shift a majority of its repayment risk under the CJR model to a different entity would fundamentally change the model CMS seeks to test. Further, our experience with other episode payment models, particularly Models 2 and 3 of BPCI, has demonstrated that relatively few PGPs have committed to assuming downside risk in those models. Nearly all of the PGPs participating in Models 2 and 3 of BPCI are participating under another entity that assumes all (or a substantial majority) of the downside risk. Thus, this experience suggests to us that increasing the limits on alignment payments is unlikely to result in many PGPs assuming a greater percentage of risk than what we proposed.

Furthermore, limiting alignment payments as we proposed operates as a safeguard in much the same manner as we discuss later in this section regarding the cap on gainsharing payments. Thus, we do not agree that increasing the limits on alignment payments is appropriate at this time or necessary to test the model.

Finally, we reiterate that beneficiaries included in a CJR episode retain their full rights to choose their providers and suppliers. Participant hospitals and CJR collaborators that engage in sharing arrangements may not adversely impede those rights of the beneficiary. Alignment payments, or the potential for such payments, must not induce the participant hospital, CJR collaborators, or the employees, contractors, or designees of the participant hospital or CJR collaborators to reduce or limit medically necessary services to any Medicare beneficiary. Individual physician and nonphysician practitioners, whether or not a party to a sharing arrangement, must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

*Comment:* Many commenters opposed the proposed cap on the total amount of gainsharing payments for a calendar year that could be paid to a PGP, or an individual physician or nonphysician practitioner who is a CJR collaborator, arguing that the 50 percent figure is arbitrary and should be removed. Other commenters asserted that a PGP that is a CJR collaborator should have the freedom to determine the most appropriate way to distribute gainsharing payments, given the multiple disciplines involved in patient care. Additionally, some commenters requested that internal cost savings be treated separately from reconciliation payments under the cap on gainsharing payments. These commenters attempted to differentiate these two revenue streams by explaining that while internal cost savings may be achieved by the participant hospital relatively early in the model, reconciliation payments are based upon changes in payment made to providers for services related to episodes in the CJR model. The commenters noted that the financial effects of these latter changes, in the form of positive reconciliation payments, may not be realized for some time. These commenters added that gainsharing payments comprised of internal cost savings are derived from hospital cost improvements and do not result from or impact Medicare payments. Thus, in the commenters' opinion, the cap on gainsharing payments should apply only to the portion of a gainsharing payment derived from a reconciliation payment. A commenter further added that the many requirements that CMS proposed, including that all payments must be auditable by HHS, provide assurance that the distribution will be documented and supported, thus avoiding the possibility of program abuse.

Other commenters acknowledged the necessity for a cap on gainsharing payments, but urged CMS to apply the same cap to the CJR model as is applied to Model 2 of the BPCI initiative, which does not place a cap on gainsharing payments to PGPs. Commenters stated that having different policies between the models could create the potential for an uneven playing field across CJR participant hospitals and BPCI Model 2 episode initiator hospitals. These commenters asserted that the cap on gainsharing payments to PGPs in CJR may work to the detriment of participant hospitals, as compared to hospitals in the same geographic markets that are participating in BPCI. Given the proposed cap on gainsharing payments to PGPs, the commenters stated that participant hospitals in CJR may be placed at a competitive disadvantage within the market, with the potential for PGPs to view hospitals in BPCI Model 2 as more lucrative financial partners.

In addition, some commenters objected to the proposed requirement that only CJR collaborators that actually furnish a service to a CJR beneficiary during an episode of care would be eligible to receive a gainsharing payment. This policy would prohibit, for example, a PGP from distributing any portion of a received gainsharing payment to physicians or nonphysician practitioners who did not furnish a service to the CJR beneficiary during an episode of care. Commenters suggested that such a requirement might be difficult to institute with PGPs and may necessitate group practices amending their particular bylaws and internal contracts. Another commenter acknowledging that CMS' rationale for this proposal was to preserve program integrity and ensure that individuals who did not furnish services to a CJR beneficiary during an episode are not permitted to receive a payment, nevertheless also disagreed with the proposal, stating that billing records do not always capture all of the surgeons who deliver care to each beneficiary, as other PGP members would likely deliver some postoperative services that are not separately recorded and thereby not identifiable from claims data. According to the commenter, only at the PGP level would it be feasible for the group members to most appropriately allocate gainsharing payments.

*Response:* We acknowledge the many perspectives of the commenters on the proposed cap on gainsharing payments to physicians, nonphysician practitioners, and PGPs in the CJR model. The purpose of the cap is to serve as a safeguard against the potential risks of stinting, steering, and denial of medically necessary care due to financial arrangements specifically allowed under the CJR model by providing an upper limit on the potential additional funds a physician, nonphysician practitioner, or PGP can receive for their engagement with participant hospitals in caring for CJR model beneficiaries beyond the FFS payments that those suppliers are also paid and that are included in the actual episode spending calculation for the episodes.

While we appreciate the distinction being made by the commenters regarding the potential timing differences between internal cost savings and reconciliation payments, as well as that internal cost savings that could be paid to a CJR collaborator would not actually be due to a change in Medicare payment, as would be the

case for reconciliation payments, we do not agree that it would be appropriate to exclude gainsharing payments based on internal cost savings from the cap on this basis. There is the potential for stinting, steering, or denial of medically necessary care to be implicated by the sharing of either internal cost savings or reconciliation payments. For example, if a physician were to discharge a beneficiary from the hospital earlier than medically necessary, and not transfer that beneficiary to PAC services that were medically necessary, such behavior could have impacts on both a hospital's internal cost savings and reconciliation payments. We do not agree that only reconciliation payments should be subject to the cap on gainsharing payments, but rather that the cap on gainsharing payments should apply to all potential dollars that could be transferred to a CJR collaborator subject to the cap. We believe that allowing a physician or nonphysician practitioner to be paid up to 50 percent more for engagement with the episode care of CJR beneficiaries than they are paid for furnishing direct services to those beneficiaries under the MPFS provides participant hospitals with substantial flexibility in developing meaningful financial arrangements that align the financial interests of physicians and nonphysician practitioners with the quality and cost goals of the hospital under the CJR model. Moreover, we note that we have applied the 50 percent cap on gainsharing payments to physicians and nonphysician practitioners in the BPCI initiative, and participants have not voiced significant complaints that this moderate financial limitation has hampered their ability to engage physicians and nonphysician practitioners in care redesign to improve episode quality and reduce costs. Given this feedback, and that the provisions governing financial arrangements for the BPCI initiative and the CJR model are similar, we believe that the 50 percent cap on gainsharing payments is an appropriate condition for this model.

We understand the perspective from some commenters that the cap on gainsharing payments to PGPs may have impacts on revenue sharing within PGPs, particularly for multi-specialty practices. If the CJR model included clinical episodes for many different conditions, such as in the case of a number of BPCI participants who are testing multiple different clinical episodes, we could understand how it might be justified to remove the cap on gainsharing payments to PGPs. However, with CJR, there is only a single episode—LEJR procedures. As such, we believe it is likely that most services to CJR beneficiaries during an episode will be furnished by an identifiable subset of physician and nonphysician practitioners within a PGP. From our experience with other bundled payment models, such as the BPCI initiative, we have found that even in large, multi-specialty PGPs, the majority of services to LEJR patients are furnished by a subset of practitioners.

We proposed that a cap on gainsharing payments made to a PGP that is a CJR collaborator be limited by the aggregate billable services furnished during a calendar year to the participant hospital's CJR beneficiaries during CJR episodes by physicians and nonphysician practitioners that are members of the PGP. This cap on gainsharing payments to PGPs is based on Medicare payments for the services delivered to CJR beneficiaries by PGP members. We also proposed that the only PGP members that could receive all or a portion of the gainsharing payment made to the PGP are those PGP members that furnished a billable service to a CJR beneficiary during a CJR episode. Therefore, we believe that the cap on gainsharing payments as it has been proposed for the CJR model is appropriate, because it ensures that only physicians and nonphysician practitioners within a PGP that may receive all or a portion of a gainsharing payment are those physicians and nonphysician practitioners who actually furnished services to CJR beneficiaries during CJR episodes, and that the amounts those PGP members receive does not exceed the capped amounts that would be applied to those physician and nonphysician practitioners if they were directly engaging with a participant hospital as CJR collaborators.

For example, for a physician or nonphysician practitioner who furnishes billable services in a calendar year to CJR beneficiaries during CJR episodes that amount $1,000 in total Medicare approved amounts under the MPFS, the cap for that physician or nonphysician practitioner would be $500. By comparison, if the physician or nonphysician practitioner furnishes billable services in a calendar year to CJR beneficiaries during CJR episodes that amount $0 in total Medicare approved amounts under the MPFS, the cap for that physician or nonphysician practitioner would be $0. In both scenarios, if the physician or nonphysician practitioner is a PGP member in a PGP that is a CJR collaborator that has a sharing arrangement with a participant hospital, then the maximum gainsharing payment that could be made to the PGP would be the aggregate capped amounts, as previously described, of all physician and nonphysician practitioners that furnished a billable service in a calendar year to a CJR beneficiary during a CJR episode. Similarly, if the physician or nonphysician practitioner has a sharing arrangement directly with a participant hospital (regardless of whether the physician or nonphysician practitioner is a PGP member), the maximum gainsharing payment that could be made to the physician or nonphysician practitioner would be the capped amount, as previously described, for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner. We believe that the flexibilities inherent in these policies on limits to gainsharing recognize the various levels of engagement from physicians and nonphysician practitioners in a participant hospital's care redesign, and allows for arrangements to be structured accordingly.

Our proposed policies for limits on gainsharing also recognized that the work of care redesign will also likely be carried out by those same physicians caring for model beneficiaries. We further note that MSAs with high proportions of acute care hospitals initiating LEJR episodes in BPCI have not been included in the random selection process for the CJR model, as described in section III.A. of this final rule. This should limit those communities where participant hospitals in CJR and BPCI hospitals initiating LEJR episodes are co-located such that PGPs could consider moving their current practice locations based on financial considerations under a model in testing.

Furthermore, we do not see how allowing all or a portion of a gainsharing payment to be distributed to individual physicians, nonphysician practitioners, or members of PGPs who did not furnish any services to model beneficiaries during a CJR episode is likely to increase the quality of care that was furnished to those beneficiaries or reduce the cost to Medicare. We can, however, see the potential for abuse by allowing such payments to flow freely to any member of a PGP, as PGPs in some markets could potentially funnel portions of a gainsharing payment to practitioners not involved in LEJR care as a means of impacting the referral patterns of those practitioners to particular hospitals or the PGP. As stated previously, the cap on gainsharing payments functions to deter

steering, stinting, and denial of medically necessary care. For these reasons, we believe that the limits on gainsharing payments to certain types of CJR collaborators via the proposed cap are necessary and tailored appropriately to the risks we seek to minimize.

In summation, the cap on gainsharing payments ensures that only physician and nonphysician practitioners that actually furnish a service to a beneficiary during a CJR episode are eligible for gainsharing payments, and that gainsharing payments made to PGPs are limited to the aggregate capped amounts of each physician or nonphysician practitioner member that furnished a service to a CJR beneficiary. We reiterate that while the cap is only applicable to gainsharing payments made to CJR collaborators who are physicians, nonphysician practitioners, providers or suppliers of outpatient therapy services, and PGPs, CJR collaborators that are SNFs, HHAs, LTCHs, IRFs, physicians, nonphysician practitioners, and providers or suppliers of outpatient therapy services that are CJR collaborators must have furnished a billable service during a CJR episode to a CJR beneficiary during the calendar year in which the internal cost savings was generated or to which the NPRA applied (the latter of which are directly reflected in a reconciliation payment), in order to be eligible to receive a gainsharing payment. As discussed later in this section, CJR collaborators that are PGPs need to have participated in care redesign activities that involved the provision of care to CJR beneficiaries during the calendar year in which the internal cost savings was generated or to which the NPRA applied (the latter of which is directly reflected in a reconciliation payment), in order to be eligible to receive a gainsharing payment. We believe this connection to beneficiaries is likely to be important in aligning the financial incentives of the practitioner with those of the participant hospital, as well as the other providers and suppliers involved in the delivery of care to beneficiaries.

*Comment:* A commenter suggested that outside of large orthopedic groups, few CJR collaborators are likely to have a sufficient volume of cases for gainsharing to be a financially meaningful incentive. The commenter further explained that in the current environment, there is no compelling reason for a CJR collaborator to enter into a sharing arrangement containing provisions for alignment payments.

Many commenters offered related comments regarding CMS' proposed gainsharing policies as applied to PGPs. Commenters vigorously requested that CMS remove the provision prohibiting a PGP that is a CJR collaborator from retaining any portion of a gainsharing payment. CMS' proposal would have required the PGP to distribute 100 percent of the gainsharing payment to the PGP's member physicians and nonphysician practitioners that actually furnished a service to a CJR beneficiary during a CJR episode. In opposing this proposed requirement, commenters stressed that PGPs should have the freedom to determine the most appropriate way to distribute gainsharing payments, given the multiple disciplines involved in patient care, and the potential for clinical and financial involvement of the PGP in the care of CJR beneficiaries. Multiple commenters suggested that if CMS were to finalize this proposal without modification that PGPs would likely be discouraged from participating as CJR collaborators in the model.

*Response:* We appreciate these perspectives, and have carefully considered the potential consequences of our proposals. With regard to the commenter that recommended that gainsharing will be meaningful for only a small subset of large PGPs, our experience in gainsharing in other models suggests otherwise. For example, we have received extensive feedback from participants in the BPCI initiative that gainsharing can be a highly effective tool in assisting hospitals in aligning financial incentives not only with physician group practices, but also with individual physicians. Second, as we detail in section III.C. of this final rule, PAC spending within a 90-day LEJR episode constitutes a significant portion of the overall episode spending. As a result, we believe that participant hospitals may choose to engage in sharing arrangements with a wide variety of CJR collaborators, including physicians, PGPs, and PAC providers to attempt to reduce unnecessary episode spending during the post-anchor hospital discharge period. Our experience with BPCI suggests these efforts may be best served from involvement by multiple individuals and entities, not just large orthopedic practices.

We considered whether PGPs that are CJR collaborators should be permitted to retain all or a portion of a gainsharing payment. We are concerned by the comments suggesting that some PGPs may be unwilling to engage in care redesign efforts as a CJR collaborator with a participant hospital if the PGP is not permitted to retain a gainsharing payment. We also understand that PGPs might serve a variety of functions that contribute to care redesign and innovations in care furnished to CJR beneficiaries. For example, while a PGP, as an entity, would not furnish a billable service to a CJR beneficiary (that function is performed by the member physician and nonphysician practitioners of the PGP), a PGP that is engaged in care redesign with a participant hospital could serve as an organizing entity for the physician and nonphysician practitioner members of the PGP that are furnishing services to CJR beneficiaries. Further, the PGP might provide care coordination services for CJR beneficiaries or invest in new technologies that improve care for CJR beneficiaries. In this way, a PGP is distinct from the other provider and supplier types eligible to be CJR collaborators in that, although the PGP is a Medicare enrolled entity, it does not furnish billable services to beneficiaries.

Given these considerations, we are persuaded that a PGP that is a CJR collaborator should be permitted to retain all or a portion of a gainsharing payment. Thus, we are finalizing our proposal with a modification to allow PGPs that are CJR collaborators to retain all or a portion of a gainsharing payment that the PGP receives from a participant hospital. We believe that this modification will provide greater financial flexibility to PGPs that are CJR collaborators, and will allow for those PGPs to consider sharing arrangements that contain provisions regarding alignment payments. We note that for purposes of this final rule, a PGP is an entity that furnishes clinical patient care services, including evaluation and management services, or professional surgical services. We do not believe that an entity is a PGP if it merely furnishes supplies or tests to patients.

In order to be eligible to receive a gainsharing payment, the PGP that is a CJR collaborator must meet all of the following:

- The PGP must have at least one member of the PGP that is a physician or nonphysician practitioner, as those terms are defined at § 510.2, that actually furnished a service to a CJR beneficiary during a CJR episode during the calendar year in which the participant hospital's internal cost savings was generated, or to which the NPRA applied (the latter of which is directly reflected in a reconciliation payment), as these funds are the only two sources that may comprise a gainsharing payment;
- The PGP must contribute to a participant hospital's care redesign in CJR and be clinically involved in the care of CJR beneficiaries. The following is a non-exhaustive list of ways in

which a PGP might be clinically involved in the care of CJR beneficiaries:

++ Provide care coordination services to CJR beneficiaries during and/or after inpatient hospital admission;

++ Engage with a participant hospital in developing care redesign strategies, and actually perform a role in implementing such strategies, that are designed to improve the quality of care for LEJR episodes and reduce LEJR episode spending;

++ In coordination with other providers and suppliers (such as the PGP's members, participant hospitals, and PAC providers), implement strategies designed to address and manage the comorbidities of CJR beneficiaries.

Finally, should the PGP wish to distribute all or a portion of a gainsharing payment to its member physicians and nonphysician practitioners, we discuss later in this section, in detail, the requirements for such distributions.

*Comment:* Multiple commenters raised issues related to participant hospitals' consideration of quality of care in initially selecting CJR collaborators and later determining gainsharing payments for CJR collaborators. While some commenters recommended that CMS require hospitals to engage in sharing arrangements with all providers and suppliers caring for CJR model beneficiaries, other commenters encouraged CMS to maintain participant hospital flexibility in selecting CJR collaborators based on parameters such as contributions to the efficiency and quality of episode care.

With respect to the determination of gainsharing payments, a commenter stated that gainsharing payments should be founded in quality performance, with each CJR collaborator needing to meet minimum thresholds prior to any gains being distributed. Other commenters suggested that the ability of all CJR collaborators to receive a gainsharing payment should be based on the quality performance of the CJR collaborators both as individuals and as a group—essentially recommending that CMS institute a ''quality gate'' that would need to be met by all CJR collaborators in order for any single CJR collaborator to receive a gainsharing payment. The suggested methodologies varied as to how quality would be measured—some commenters suggested that selection should be done by CMS while others recommended that participant hospitals should choose quality criteria important to them. Commenters did not suggest particular quality criteria that CMS should consider, and most commenters did not describe how CMS or participant hospitals would select quality criteria.

*Response:* We agree with commenters that quality should be a consideration in the participant hospital's selection of CJR collaborators, as well as the determination of gainsharing payments for CJR collaborators. However, we do not believe that we need be as prescriptive on quality criteria used for determining gainsharing payments as some commenters suggested. Participant hospitals are best positioned to determine the quality of care considerations for CJR collaborator selection and the quality criteria for gainsharing payments that are most important to them and that are the most meaningful indicators of the quality of care furnished to CJR model beneficiaries. By way of comparison, BPCI participants are required to report the quality targets they will use in determining gainsharing payments, and providers and suppliers who do not meet the BPCI participant's quality targets are prohibited from receiving gainsharing payments. For the CJR model, we are adopting a more flexible approach to quality considerations in the selection of CJR collaborators and the requirement that quality criteria be described in sharing arrangements under the CJR model, once again balancing our interest in encouraging financial arrangements that consider high quality of care and not the volume and value of referrals, with allowing participant hospitals maximal flexibility to determine the issues related to quality of most importance to their efforts to improve episode quality and efficiency.

With regard to the selection of CJR collaborators, while we do not agree with the commenters suggesting that we require participant hospitals to engage as CJR collaborators with all providers and suppliers caring for CJR model beneficiaries, we believe the providers and suppliers that the participant hospital selects as CJR collaborators should be held to certain standards related to the quality of care for CJR model beneficiaries. Thus, we believe it is appropriate to require the participant hospital to create a written set of policies for selecting providers and suppliers for sharing risks and gains as CJR collaborators. Those policies must be related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode. We believe these criteria could permit selection of CJR collaborators based on their previous demonstration of the ability to furnish high-quality services to beneficiaries receiving LEJR or based on their expected high quality care due to requirements specified in the hospital's collaborator agreement. For example, some participant hospitals may choose to satisfy this requirement by adopting quality criteria that look at a provider/supplier's past performance on certain quality metrics, such as complication rates, whereas other hospitals may choose to adopt quality criteria that rely primarily on satisfaction of forward-looking requirements that the participant hospital expects to lead to improved quality of episode care, such as attending weekly care coordination meetings, contacting CJR beneficiaries frequently, or following specified clinical care pathways. As previously stated, we believe it is important that participant hospitals have the ability to select the CJR collaborators that are willing to engage in the participant hospital's care redesign strategies, as well as provide high-quality care, so that the CJR collaborators are likely to contribute to improvements in episode quality and efficiency. Thus, with regard to the role of quality in the selection of CJR collaborators, we will require the participant hospital to develop a written set of criteria that it will use to determine the selection of all CJR collaborators.

We also believe the quality of care furnished by CJR collaborators to beneficiaries during an episode should be a factor in determining a gainsharing payment, not just the savings created by the CJR collaborator. We believe that requiring participant hospitals to include quality criteria when determining gainsharing payments will incentivize CJR collaborators to provide high quality, medically necessary care that contributes to the quality of episode care. Because the CJR model incorporates pay-for-performance in the payment methodology, rewarding high quality performance and quality improvement with increased financial opportunity for participant hospitals as discussed in section III.C.5. of this final rule, we believe this same principle should carry through to gainsharing payments, to which episode quality and cost performance should be linked. We further believe that requiring the participant hospital to include quality criteria as a factor in the determination of gainsharing payments should prevent low quality providers and suppliers that have not contributed to the quality of episodes that leads to participant hospital financial opportunity from receiving gainsharing payments in this model.

With regard to the role of quality in the determination of gainsharing

payments, we will require the participant hospital to develop a written methodology included in the collaborator agreement that specifies how the hospital will determine gainsharing payments. To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria, established by the participant hospital and directly related to CJR episodes of care, for the calendar year for which the gainsharing payment is determined. For purposes of this requirement, we note that participant hospitals may utilize a variety of quality criteria depending on their priorities for care redesign and quality improvement, as long as those criteria are directly related to CJR episodes of care. For example, some participant hospitals may choose to incorporate health outcome measures specific to each CJR collaborator in the gainsharing methodology, such as the hospital readmission rate of CJR beneficiaries for each physician or the complication rate of CJR beneficiaries at each SNF, in their quality criteria for gainsharing payments. Other hospitals may choose to incorporate specific process measures that are aligned with the hospital's objectives for care redesign to improve CJR episode quality, such as the rate of attendance by CJR collaborators at weekly care coordination meetings to discuss the care of CJR beneficiaries or performance on patient experience surveys of CJR model beneficiaries. Again, we underscore that the set of quality criteria used to determine gainsharing payments must be directly related to the care of CJR beneficiaries, but we believe that each hospital should be permitted to determine the quality criteria most important to them and which relate to the areas of care redesign on which they seek improvement.

In summary, we will require the participant hospital to develop and maintain a written set of policies for selecting its CJR collaborators. Further, this set of policies must contain criteria for selection of CJR collaborators that include criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries by the CJR collaborator during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or revenue generated by providers or suppliers. All CJR collaborators must have met, or agree to meet, the quality criteria for selection. In the case of selection criteria regarding an individual's or entity's willingness to engage in activities that are expected to improve the quality of care (such as following specified clinical pathways), such activities must be specified in the collaborator agreement as an obligation of the CJR collaborator. We are also adding a requirement that the participant hospital include in its collaborator agreements with CJR collaborators the methodology the participant hospital will use to determine gainsharing payments, and this methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode, and not directly on the volume or value of referrals or business generated by providers and suppliers. Finally, we will require participant hospitals, in considering the quality criteria to incorporate as part of their gainsharing methodologies, to use quality criteria that are directly related to CJR episodes of care, so that the criteria used by the participant hospital are relevant to care for beneficiaries in the model. To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria for the calendar year for which the gainsharing payment is determined by the participant hospital. Any CJR collaborator that does not meet the quality criteria described with specificity in the collaborator agreement is not eligible for a gainsharing payment for the calendar year for which the gainsharing payment is being calculated.

Lastly, with regard to the application of a participant hospital's quality criteria prior to the distribution of gainsharing payments, we are clarifying our proposal by changing the word ''calculation'' to ''determination.'' As previously discussed, we are requiring that participant hospitals use a methodology to determine gainsharing payments, and that this methodology be explained in detail in all sharing arrangements with CJR collaborators. We expect that this methodology may include calculations, but we are clarifying that while quality criteria must be used when determining the gainsharing payment for each CJR collaborator, the quality criteria are not specifically required to be a part of the calculated amount of the gainsharing payment.

*Comment:* Many commenters recommended specific changes to the gainsharing policies proposed by CMS. First, some commenters recommended that CMS require participant hospitals to offer the same gainsharing arrangement to all CJR collaborators of the same provider or supplier type. For example, MedPAC recommended that CMS allow participant hospitals the flexibility to draft their own risk-sharing arrangements, but require that hospitals have the same gainsharing arrangement with all physicians; the per-episode payment for each physician that is a CJR collaborator in the gainsharing pool would be the same. MedPAC also suggested that physicians in a gainsharing pool should be judged across all CJR beneficiaries treated by all physicians in the pool, which would prevent hospitals from making gainsharing payments on a patient-specific basis. MedPAC stated that these requirements would limit the incentive for physicians to select low-cost patients. With respect to CJR collaborators that are PAC providers, MedPAC and other commenters recommended that participant hospitals should not be required to offer risk sharing to all PAC providers, the arrangements offered should be identical across all selected PAC providers, and the gainsharing payments should be calculated for all PAC providers offered risk sharing by the hospital using a methodology that is not patient-specific or provider/supplier-specific. The commenters recommended that gainsharing methodologies that reward providers or suppliers based on the performance of a group of similar providers or suppliers would limit the incentives for certain CJR collaborators to select low-cost patients over higher cost patients. In addition, the commenters recommended that such methodologies would encourage all CJR collaborators to lower episode spending, improve quality, and reduce Medicare spending for all CJR model beneficiaries.

Second, a number of commenters urged CMS to make sharing arrangements mandatory; in effect suggesting that participant hospitals be required to enter into gainsharing relationships. For example, a commenter recommended that CMS require participant hospitals to enter into sharing arrangements with ACOs in the participant hospital's MSA. Another commenter recommended that CMS require participant hospitals to enter into sharing arrangements with all orthopedic physicians credentialed at the hospital, in order to reduce the potential for hospitals to arbitrarily decide whether or not to enter into such arrangements with a physician. Multiple commenters cautioned that participant hospitals may choose to select only the most ''efficient'' or ''cost effective'' orthopedic surgeons to enter into sharing arrangements, and thus recommended that CMS require participant hospitals to enter into sharing arrangements with all

physicians. Another commenter likewise urged CMS to require, or strongly encourage, participant hospitals to collaborate with independent professionals who can demonstrate effectiveness and efficiency in the rehabilitation treatment of THA and TKA patients in the model. However, many other commenters recommended that CMS retain the provision in the proposed rule to allow participant hospitals the freedom to determine whether they want to enter into gainsharing or risk-sharing arrangements. MedPAC stated that a participant hospital should not be required to offer sharing arrangements to all providers and suppliers in its market, and that participant hospitals should be allowed to exclude providers and suppliers that are not contributing to efficiencies or that are delivering a poor quality of care. Many commenters recommended that CMS allow participant hospitals to discontinue a sharing arrangement with any individual or entity not contributing to savings. Several commenters urged CMS to finalize its proposed policy to prohibit participant hospitals from coercing or requiring physician participation in the CJR model.

Many commenters stated that the proposed sharing arrangement requirements, such as the gainsharing and alignment payment caps, were too limiting. Several commenters noted that certain types of physicians—particularly orthopedic surgeons—serve a critical role in care redesign and creating internal cost savings for a participant hospital and episode savings to Medicare. Thus, these commenters stated, applying the same policies regarding sharing gains and losses to orthopedic surgeons as to other providers and suppliers—such as physical therapists or PAC providers—would be inapplicable. These commenters recommended that CMS allow physicians greater freedom to negotiate sharing arrangements—such as the ability to assume greater financial risk above the 25 percent for alignment payments proposed by CMS in the proposed rule, and removal of the 50 percent cap on gainsharing payments for CJR collaborators that are physicians, nonphysician practitioners, and PGPs.

Several commenters suggested that the proposed caps on gainsharing payments and alignment payments were arbitrary, particularly given the proposed policy that gainsharing payments must be ''actually and proportionally related to the care'' of beneficiaries in CJR episodes and that the CJR collaborator must be contributing to the care redesign strategies of the participant hospital. Other commenters likewise suggested that the capped limits were arbitrary because they may not reflect the efforts that a physician undertook to meet required quality metrics and reduce episode spending. Rather than setting what they argue is an arbitrary limit, these commenters recommended that CMS should allow providers to determine the distribution amounts.

Some commenters noted that gainsharing structures in the private sector allow for more flexibility and are less prescriptive. Other commenters recommended that the participant hospital should be afforded broad discretion to establish its policies for the distribution of gainsharing payments. For example, a commenter suggested that CMS should remove the requirement that gainsharing payments be made annually, and allow participant hospitals to make this payments at any interval, or at a minimum, twice per year. These commenters also noted that hospitals are likely to be experienced business entities and should be able to make independent financial decisions without a regulatory structure for gainsharing like the one proposed. Further, these commenters suggested that in the absence of gainsharing, the participant hospital would retain the full reconciliation payment, and thus the hospitals are unlikely to make distributions of gainsharing payments unnecessarily.

*Response:* We appreciate the robust response from commenters on these issues. We proposed to allow financial arrangements in this model to incentivize higher quality care and reductions in episode spending through improved financial alignment between providers and suppliers furnishing services to beneficiaries during a CJR episode, while protecting against undue risk from beneficiary steering, care stinting, and inappropriate reductions in access to care that could otherwise result from the financial incentives in an episode payment model.

We appreciate the reasons for the recommendations by some commenters that we require participant hospitals to essentially offer the same gainsharing arrangement to all providers and suppliers of the same type. While we understand the potential benefits of a policy standardizing sharing arrangements to protect against selection of low-cost patients and the resulting patient steering, we believe that participant hospitals may have legitimate reasons to enter into a sharing arrangement with a particular provider or supplier that differs from the hospital's arrangements with other similar providers or suppliers. For example, it is possible there may be instances in which a particular SNF offers certain therapies or has resources that a participant hospital believes will benefit its patients in the model. In these instances, it may be prudent for a hospital to enter into a different sharing arrangement with that SNF, as opposed to other SNFs. Furthermore, participant hospitals may have legitimate reasons to construct different sharing arrangements with CJR collaborators that agree to take on a portion of the participant hospital's financial risk compared to sharing arrangements with CJR collaborators that do not assume downside risk. We believe that the CJR model's policies that require participant hospitals to be financially liable for episodes of care will incentivize participant hospitals to decrease episode spending and increase the quality of care by engaging participant hospitals to seek CJR collaborators that are also supportive of these goals.

We believe that the MedPAC recommendation to require identical per-episode payments for each physician that is a CJR collaborator would likely limit physician commitment to the goals of the model and the model would be less likely to result in reduced episode spending and improved quality of care. Our experience in other models that incorporate gainsharing has indicated that a hospital may have legitimate reasons to construct different sharing arrangements with different physicians, depending on factors such as the involvement of the physician in the hospital's care redesign efforts, adoption of leadership roles requiring direction and instruction of other physicians, and the number and magnitude of disruptions in the physician's existing practice patterns.

We have included safeguards in this final rule to address patient steering, including the requirement that beneficiaries retain their full rights to choose their providers and suppliers, the requirement that hospitals not limit beneficiary choice of providers or suppliers, the cap on gainsharing payments, the requirement that the opportunity to receive gainsharing payments (or the opportunity to make or receive alignment payments) may not be conditioned on the volume or value of past or anticipated referrals or other business generated to, from, or among the participant hospital and any CJR collaborator, the requirement that gainsharing payments be distributed only to CJR collaborators that meet the quality criteria established by the participant hospital, and the

requirement that gainsharing methodologies must not directly account for the volume or value of referrals or business otherwise generated between or among the participant hospital and CJR collaborators. For these reasons, we believe that participant hospitals should be allowed to enter into different sharing arrangements with various CJR collaborators.

While we appreciate the reasons why some commenters recommended that we require participant hospitals to enter into financial relationships with certain entities and individuals, we do not agree that such a requirement is necessary. We agree with the commenters who supported the voluntary nature of sharing arrangements, and we continue to believe that it is essential that sharing arrangements be voluntary and without penalty for nonparticipation. Although we are not requiring participant hospitals to offer sharing arrangements to all providers or suppliers, we are finalizing our proposal prohibiting hospitals from coercing or requiring individuals or entities to enter into a sharing arrangement, and participant hospitals may not penalize or discriminate against physicians and nonphysician practitioners on the grounds that they are not CJR collaborators. However, in response to these comments, we are also modifying our proposal, discussed in detail later in this section, regarding the selection criteria a participant hospital must use in choosing CJR collaborators. We believe that our final requirement for selection criteria for CJR collaborators responds to the concerns from some commenters regarding how a participant hospital selects it CJR collaborators.

In response to the view of some commenters that the provisions for gainsharing and risk-sharing in the CJR model are overly restrictive, we note that we constructed a framework for financial arrangements in the CJR model that we believe leaves participant hospitals and CJR collaborators relatively unconstrained to develop sharing arrangements in a manner they see fit, provided that all the requirements contained in this final rule are met. We have not proposed that participant hospitals would need to use a particular methodology for determining gainsharing payments or alignment payments, other than placing upper thresholds on those payments and a requirement for quality criteria for gainsharing payments, which we discuss in greater detail previously in this section.

With regard to the provision on the annual distribution of gainsharing payments, given that CMS is not requiring participant hospitals to submit gainsharing methodologies for review or to report gainsharing payments to CMS, we believe that the provision allowing for gainsharing payments on an annual basis is appropriately placed, for purposes of tracking by the participant hospital, as well as facilitating any program integrity matters by CMS, HHS, and its designees. We also believe that annual distributions of gainsharing payments are appropriate because reconciliation within the model will occur on an annual basis. Also, because providers and suppliers will continue to be paid according to the existing FFS processes throughout the duration of the model, CJR collaborators will continue to have sources of revenue other than gainsharing payments, which we believe makes distributions of gainsharing payments more often than once per year unnecessary. Finally, while gainsharing arrangements in the private sector may be less restrictive, as suggested by some commenters, other commenters nonetheless noted that a number of Federal laws are implicated by gainsharing, and thus a more prescriptive set of gainsharing policies is an appropriate reflection of the presence and importance of that legal framework. We agree with those commenters, and emphasize that while we have attempted to avoid making the provisions on sharing arrangements and collaborator agreements unnecessarily complex, we believe that the regulatory requirements for these documents are justified, for reasons such as limiting opportunities for patient steering, preserving beneficiary choice, and protecting Federal healthcare dollars.

We continue to believe that the permissible sharing arrangements under the CJR model should allow participant hospitals substantial and appropriate flexibility to develop these arrangements with the care redesign needs of their beneficiaries in mind to achieve the model objective of quality improvement and reduced episode cost, while providing sufficient protections against the possible risks of beneficiary steering, stinting, and inappropriate reductions in access to care under an episode payment model. Therefore, final policies apply certain limited protections to minimize these risks and reduce the opportunities for providers and suppliers to engage in inappropriate behavior, while allowing participant hospitals sufficient flexibility to achieve success in the model, striking an appropriate balance between these two important objectives. These protections fall into the following several categories:

- Requirements that the basis for selection of CJR collaborators be on criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode, and that the selection criteria cannot be based directly or indirectly on the volume or value of referrals or revenue generated by providers or suppliers. Further, all CJR collaborators must have met, or agree to meet, the quality criteria for selection.
- Requirements that the basis for, and determination of, gainsharing payments include provisions describing with specificity in the collaborator agreement, including the quality criteria that the participant hospital will use in its determination of gainsharing payments, and that such payments be based on criteria other than the volume or value of past or future referrals, or business otherwise generated.
- Contemporaneous documentation requirements to ensure that collaborator agreements between participant hospitals and CJR collaborators are memorialized in writing and comply with all the provisions of this final rule.
- Limits on the absolute amount of dollars in alignment payments to ensure that such payments are made solely for the purposes permitted under this final rule.
- Restrictions on the types of providers and suppliers that may receive gainsharing payments and provisions requiring that those providers and suppliers have actually furnished a service to a beneficiary and/or been involved in care redesign, as required by this final rule.
- Limits on the absolute amount of dollars an individual practitioner or PGP may receive as gainsharing payments.
- Compliance from participant hospitals and CJR collaborators with the requirements of this final rule.

Finally, for the many reasons previously provided, we disagree with commenters who suggested that we proposed an arbitrary structure for financial arrangements in the CJR model. We acknowledge that any protections will inherently provide some limits on the flexibility of participant hospitals to develop certain financial arrangements, but we believe that the CJR model requirements appropriately balance the need for flexibility and program integrity.

*Comment:* Some commenters expressed confusion about the manner in which gainsharing payments can be distributed from participant hospitals to CJR collaborators. For example, these

commenters inquired about whether a physician who is engaged in CJR model care redesign with a participant hospital and is also a member of a PGP would contract directly with the participant hospital through a collaborator agreement or whether the PGP would contract with the participant hospital, including on behalf of the physician member who is working with the hospital.

*Response:* We appreciate these requests for clarification. We understand from the comments that some physicians engaged in care redesign with a participant hospital may wish to contract directly with a hospital through a collaborator agreement, and other physicians may prefer to have their PGP contract directly with a participant hospital on behalf of the members of the PGP that furnish services to CJR beneficiaries. We note that as previously discussed, we are finalizing our proposal with a modification to allow PGPs that are CJR collaborators to retain all or a portion of a gainsharing payment, provided that the PGP meets certain conditions. A PGP that does not retain any or all of a gainsharing payment can distribute all or the remaining portion of the gainsharing payment to individual practitioners who are members of the PGP under certain conditions. As such, we are adding new § 510.505 to set forth the requirements for the arrangement between a PGP that is a CJR collaborator and the individual practitioners who are members of the PGP. The section only applies when the PGP chooses to distribute all or a portion of a gainsharing payment to individual physicians or nonphysician practitioners who are members of the PGP.

We specify in § 510.505(a) that a PGP that has entered into a collaborator agreement with a participant hospital may distribute all or a portion of any gainsharing payment it receives from the hospital only in accordance with a ''distribution arrangement,'' which we define as a financial arrangement between a PGP that is a CJR collaborator and a ''practice collaboration agent'' pursuant to which the PGP distributes some or all of a gainsharing payment. We define a ''practice collaboration agent'' as a PGP member who has entered into a distribution arrangement with the same PGP of which he or she is a member and who has not entered into a collaborator agreement with a participant hospital. We are defining the terms ''PGP member'' and ''member of a PGP'' to mean a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment. We note that the fact that an entity employs or contracts with physicians, nonphysician practitioners or therapists does not make the entity a PGP. We are adding commonplace definitions of ''physician'' and ''nonphysician practitioner'' and we are defining ''therapist'' to include physical, occupational, and speech therapists.

We emphasize that a PGP that is a CJR collaborator (hereafter in this section, ''a PGP,'' unless noted otherwise) is not obligated under this final rule to distribute (make a ''distribution payment'') of a gainsharing payment to its PGP members. Upon receipt of a gainsharing payment, the PGP may retain some or all of the gainsharing payment. If the PGP chooses to make distribution payments, it must do so only in accordance with a distribution arrangement. This final rule requires at new § 510.505 that all distribution arrangements must comply with all applicable laws and regulations, including the applicable fraud and abuse laws, and the following criteria:

- All distribution arrangements must be in a writing signed by the PGP and practice collaboration agent.
- Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.
- The distribution arrangement must require the practice collaboration agent to comply with the requirements set forth in this final rule.
- The opportunity to receive a distribution payment must not be conditioned directly on the volume or value of past or anticipated referrals or other business generated to, from, or among a participant hospital, the PGP, other CJR collaborator, any practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- Methodologies for determining distribution payments must not directly account for volume or value of referrals, or business otherwise generated, between or among the participant hospital, CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- A practice collaboration agent is eligible to receive a distribution payment only if the PGP billed for an item or service furnished by the practice collaboration agent to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP.
- Where a PGP receives a gainsharing payment from a participant hospital pursuant to a sharing arrangement, all monies contained in such a gainsharing payment must be shared only with the physician or nonphysician practitioners that are PGP members that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA, as that term is defined in section III.C.6. of the final rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment.
- The total amount of distribution payments for a calendar year paid to a practice collaboration agent must not exceed 50 percent of the total Medicare approved amounts under the Medicare Physician Fee Schedule (MPFS) for services billed by the PGP and furnished by the practice collaboration agent to the participant hospital's CJR beneficiaries during a CJR episode.
- With respect to the distribution of any gainsharing payment received by a PGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment.
- All distribution payments must be made through EFTs.
- The practice collaboration agents must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.
- The distribution arrangement must not—

++ Induce a practice collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

++ Reward the provision of items and services that are medically unnecessary.

- The PGP must maintain documentation regarding practitioner distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, documentation of the amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for calculating the amount of any distribution payment.
- The PGP may not enter into a distribution arrangement with any member of the PGP that has a collaborator agreement in effect with a participant hospital.

These provisions require distribution payments to be made by a PGP only to individuals who furnished an item or service to a CJR beneficiary during a CJR

episode. As a result, a PGP's existing practice compensation methodology is likely to be inapplicable to the determination and payment of distribution payments. For example, where a PGP retains a gainsharing payment and elects not to make distribution payments to eligible practice collaboration agents, the aforementioned criteria would prohibit the PGP from placing the gainsharing payment in its general funds and distributing those monies to any member of the PGP who did not furnish an item or service to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP. We emphasize that such individuals are not permitted under this final rule to receive a distribution payment.

*Comment:* Some commenters requested that CMS offer additional protections to small businesses, such as some physical therapy or physician group practices, who may desire to engage as CJR collaborators with participant hospitals, but may have limited resources to do so. Recommendations from these commenters were for CMS to ensure that gainsharing payments are paid in a timely manner, that gainsharing payments are distributed fairly and equitably to CJR collaborators according to the provisions in this final rule as well as those agreed upon in a collaborator agreement, and that participant hospitals and CJR collaborators not be permitted to engage in unfair business practices.

*Response:* It is our intent to construct a model that offers opportunities for providers and suppliers of all sizes to be CJR collaborators, provided they meet the criteria in this final rule. In response to the timely payment comment, we direct those commenters to the requirement that gainsharing payments must be distributed on an annual basis. Accordingly, a gainsharing payment can only be distributed to eligible CJR collaborators once per year. As previously noted, CMS is not requiring participant hospitals to enter into collaborator agreements with all providers and suppliers caring for CJR beneficiaries, but where a hospital does enter one or more collaborator agreements, the participant hospital must not distribute any gainsharing payments more than once per year. We believe that this requirement ensures that gainsharing payments are timed to sufficiently maintain a CJR collaborator's commitment to lowering costs and improving quality of care.

To the extent the commenters were advocating that CMS prohibit late payment of amounts owed to CJR collaborators, we believe that the consequences for breach of contract offer sufficient protection. Regarding the commenters' desire to ensure that gainsharing payments are distributed fairly and equitably to CJR collaborators, we believe that the provisions of this final rule adequately address their comment. For example, this final rule prohibits participant hospitals and all CJR collaborators from reducing or limiting medically necessary services, prohibits conditioning the opportunity to receive gainsharing payments on the volume or value of referrals, requires gainsharing payment eligibility to include quality criteria and gainsharing payment determinations to be based on criteria related to the quality of care to be delivered to CJR beneficiaries during episodes, prohibits gainsharing methodologies that directly account for the volume or value of referrals, and caps the amount a physician or nonphysician practitioner can receive in gainsharing payments as a CJR collaborator. Finally, we agree with the commenters that it is important to deter unfair business practices, but the regulation of such practices is outside the scope of our authority. Accordingly, we decline to add a prohibition against unfair business practices. However, we believe that many of the program integrity provisions regarding sharing arrangements will also serve to deter unfair business practices.

*Comment:* A few commenters suggested that CMS should encourage participant hospitals and CJR collaborators to establish multi-year collaborator agreements, with the goal of fostering a long-term relationship resulting in optimal program alignment.

*Response:* Nothing in this final rule prohibits participant hospitals and CJR collaborators from entering into collaborator agreements for a duration of more than one year.

*Comment:* Several commenters opposed the adoption of reporting requirements for gainsharing and alignment payments, a topic upon which CMS sought comment but did not make a specific proposal. Alternatively, these commenters recommended CMS should not finalize the adoption of reporting requirements without considering the administrative burden such reporting would place on hospitals. However, other commenters recommended that CMS take a more active role in managing the agreements and payments between participant hospitals and CJR collaborators. For example, some commenters recommended that all collaborator agreements should be submitted to CMS and that CMS should perform random audits of these agreements to ensure they comply with current regulations. Another commenter urged CMS to track all gainsharing payments from participant hospitals to each CJR collaborator. Furthermore, multiple commenters recommended that CMS include a requirement that participant hospitals submit to CMS, or publish themselves, a list of all CJR collaborators. These commenters believe that disclosure of all sharing arrangements would foster transparency regarding the business and referral networks of providers and suppliers that may arise through sharing arrangements.

*Response:* We appreciate the feedback with respect to the potential burden of periodically reporting data to CMS on matters related to gainsharing payments. We proposed to require participant hospitals to retain documentation regarding sharing arrangements and solicited comments on whether we should require participant hospitals and CJR collaborators to periodically report certain data, including gainsharing payments, alignment payments, identification of all CJR collaborators, and other relevant information related to collaborator agreements and sharing arrangements. We also sought comment on whether we should require reporting of any other information that would assist HHS with enforcement of the regulations governing this model and whether additional or different safeguards are needed to protect the program and to ensure that its goals are satisfied.

We agree with the commenters that transparency is important to ensure program integrity and to assist with evaluation of the model. We have tried, where possible, to ensure transparency regarding sharing arrangements and distribution arrangements without imposing undue administrative burden on the individuals and entities that enter into such arrangements.

Because documenting financial arrangements is consistent with general business practices, we believe that our documentation requirement imposes minimal additional administrative burden on participant hospitals and CJR collaborators. To promote transparency, we are modifying our regulation text to require contemporaneous documentation of collaborator agreements. This will discourage gaming by ensuring that these agreements are entered into before care is furnished to CJR beneficiaries.

Further, we are modifying our regulation text to require that the documentation for collaborator agreements must include a description of the sharing arrangement; its date; the purpose; the provisions and scope of the arrangement; and the financial terms of the arrangement. We believe that these requirements will ensure that these agreements are entered into before the care furnished to CJR beneficiaries and will be auditable by the government. We have imposed similar requirements for distribution arrangements.

We do not agree that it is necessary for participant hospitals to submit periodically to CMS documentation regarding sharing arrangements, lists of CJR collaborators, or documentation regarding all gainsharing payments and alignment payments. We are sensitive to the potential burden of such a reporting requirement. We believe that the goals of transparency and program integrity can be achieved by requiring participant hospitals and CJR collaborators to retain contemporaneous documentation of collaborator agreements, gainsharing payments, and alignment payments for at least 10 years following completion of the arrangement and to allow CMS, HHS, or its designee's access to such records. In addition, we are modifying the regulation text to require each participant hospital to maintain accurate, current, and historical lists of CJR collaborators and to publish on its Web site, on a Web page accessible to the general public, an accurate and current list of all CJR collaborators. The hospital must update its published list of CJR collaborators no less frequently than quarterly. The dollar amounts of any gainsharing payments or alignment payments need not be listed on the participant hospital's Web site.

We note that the participant hospital's records associated with tracking gainsharing payments must reflect whether the participant hospital recouped any gainsharing payments received by a CJR collaborator that contain funds derived from a CMS overpayment on a reconciliation report or because such gainsharing payments were the result of the submission of false or fraudulent data. Similarly, this final rule also requires PGPs to maintain documentation regarding distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, documentation of the amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment. We have revised the regulation text to reflect these requirements.

We do not believe that the obligation to maintain accurate current or historical lists of CJR collaborators and documentation regarding all gainsharing payments and alignment payments, imposes any significant additional burden on participant hospitals. Participant hospitals will likely maintain such lists for their own operational purposes whether or not they are required by our regulations to do so. We believe that maintaining an accurate list of all CJR collaborators and documentation regarding all gainsharing payments, alignment payments, and distribution payments is a necessary and appropriate provision for purposes of transparency, keeping beneficiaries informed, and ensuring that such information is auditable by CMS, HHS, or its designees. We also believe that such information will help inform both CMS and the public about collaborator agreements.

We leave open the possibility for future rulemaking on the issue of documentation and reporting for this model. CMS may consider additional documentation requirements, including submission of lists of CJR collaborators and practice collaboration agents to CMS at regular, ongoing intervals.

*Summary of Final Decisions:* After consideration of the public comments we received, we are finalizing the proposal with thirteen modifications. These modifications are:

- The term ''Participation Agreement'' has been changed to ''collaborator agreement''.
- The term ''CJR sharing arrangement'' has been changed to ''sharing arrangement''.
- In order for a physician or nonphysician practitioner to be a CJR collaborator, the physician or nonphysician practitioner must not have opted out of Medicare.
- PGPs that are CJR collaborators may retain all or a portion of a gainsharing payment, provided that the PGP meets all the criteria in this final rule for such retention.
- Sharing arrangements, included in collaborator agreements, must be entered into before care is furnished to CJR beneficiaries under the terms of the arrangement.
- A requirement that the participant hospital develop and maintain a written set of policies for selecting its CJR collaborators. This set of policies must contain criteria for selection of CJR collaborators that include criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital and CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator. All CJR collaborators must have met, or agree to meet, the quality criteria for selection.
- A requirement that the participant hospital include in its collaborator agreements with CJR collaborators the methodology the participant hospital will use to determine gainsharing payments, and this methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode, and not directly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital and CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator
- A requirement that the participant hospital, in considering the quality criteria to incorporate as part of its gainsharing methodologies, use quality criteria that are directly related to CJR episodes of care, so that the criteria used by the participant hospital are relevant to care for beneficiaries in the model. Any CJR collaborator that does not meet the quality criteria described with specificity in the sharing arrangement is not eligible for a gainsharing payment for the calendar year for which the gainsharing payment is being determined.
- Requirements that the participant hospital keep contemporaneous documentation of collaborator agreements.
- A requirement that the participant hospital maintain accurate current and historical lists of CJR collaborators.
- A requirement that the participant hospital publish on its Web site, on a Web page accessible to the general public, accurate current and historical lists of CJR collaborators.
- A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in CJR episodes or other integrity problems.
- A regulatory framework has been created to allow PGPs that are CJR collaborators to share all or portions of gainsharing payments with individual practitioners that are members of the PGP. These requirements are set forth in new § 510.505.

With the exception of new § 510.505, the final policies are set forth in

§ 510.500, which we have reorganized to eliminate redundancy and internal inconsistencies and to more clearly set forth the requirements for CJR sharing arrangements.

''General.'' We are finalizing at § 510.500(a) the following general requirements for all sharing arrangements that a participant hospital may elect to enter into:

- A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. Any gainsharing payments or alignment payments made pursuant to a sharing arrangement must be made only from the participant hospital to the CJR collaborator with whom the participant hospital has signed a collaborator agreement containing a sharing arrangement.
- CMS may review any sharing arrangement for compliance with the requirements of this part and to ensure that it does not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.
- Notwithstanding any sharing arrangements between the participant hospital and CJR collaborators, the participant hospital must have ultimate responsibility for fully complying with all provisions of the CJR model.
- If a participant hospital enters into a sharing arrangement, it must update its compliance program to include oversight of sharing arrangements and compliance with the requirements of the CJR model.
- The board or other governing body of the participant hospital must have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CJR Collaborators, its payment of gainsharing payments and receipt of alignment payments, and its use of beneficiary incentives in the CJR model.
- Participant hospitals must develop and maintain a written set of policies for selecting its CJR collaborators. This set of policies must contain criteria for selection of CJR collaborators that include criteria related to, and inclusive of, the quality of care to be delivered by the CJR collaborator to beneficiaries during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital and CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator. All CJR collaborators must have met, or agree to meet, the quality criteria for selection.

''Sharing Arrangements.'' We have consolidated at § 510.500(b) the criteria that each sharing arrangement must satisfy. Specifically, each sharing arrangement must comply with the following criteria:

- The sharing arrangement must be set forth in a collaborator agreement that complies with the requirements of § 510.500(c).
- The sharing arrangement must comply with all relevant laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.
- An individual or entity's participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.
- The parties must enter into a sharing arrangement before care is furnished to CJR beneficiaries under the terms of the sharing arrangement.
- To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria for the calendar year for which the gainsharing payment is determined by the participant hospital. The quality criteria must be established by the participant hospital and directly related to CJR episodes of care.
- To be eligible to receive a gainsharing payment or make an alignment payment, a CJR collaborator other than a PGP must directly furnish a billable service to a CJR beneficiary during a CJR episode that occurred in the calendar year in which the savings or loss was created.
- To be eligible to receive a gainsharing payment, a PGP that is a CJR collaborator must meet the following criteria:

++ The PGP must have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participant hospital's internal cost savings was generated, or to which the NPRA applied;

++ The PGP must contribute to a participant hospital's care redesign in the CJR model and be clinically involved in the care of CJR beneficiaries. We set forth in the regulation a non-exhaustive list of ways in which a PGP might be clinically involved in the care of CJR beneficiaries.

- No entity or individual, whether a party to a collaborator agreement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.
- Gainsharing payments, if any, must be—

++ Derived solely from reconciliation payments, or internal cost savings, or both;

++ Actually and proportionally related to the care of beneficiaries in a CJR episode;

++ Distributed on an annual basis (not more than once per calendar year); and

++ Not be a loan, advance payments, or payments for referrals or other business.

- Alignment payments from a CJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must—

++ Not be issued, distributed, or paid prior to the calculation and issuance by CMS of a reconciliation report reflecting a repayment amount; and

++ Not be a loan, advance payments, or payments for referrals or other business.

- A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the provision of substandard care in CJR episodes or other integrity problems.
- In a calendar year, the aggregate amount of all gainsharing payments distributed by a participant hospital that are derived from a CJR reconciliation payment may not exceed the amount of the reconciliation payment the participant hospital receives from CMS.
- In a calendar year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount. No alignment payments may be collected by a participant hospital if it does not owe a repayment amount.
- The aggregate amounts of all alignment payments from any one CJR collaborator to a participant hospital must not be greater than 25 percent of the participant hospital's repayment amount.
- A sharing arrangement must not induce the participant hospital, CJR collaborator, or any employees or contractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary.
- A sharing arrangement must not restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.
- The methodology for determining gainsharing payments must be based, at

least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• The methodology for determining alignment payments must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

• The total amount of a gainsharing payment for a calendar year paid to an individual physician or nonphysician practitioner who is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner.

• The total amount of gainsharing payments for a calendar year paid to a PGP that is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services that are billed by the PGP and furnished during a calendar year by members of the PGP to the participant hospital's CJR beneficiaries during CJR episodes.

• The participant hospital's determination of internal cost savings must satisfy the following criteria:

++ Internal cost savings are calculated in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book).

++ All amounts determined to be internal cost savings must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

++ Internal cost savings may not reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• All gainsharing payments and any alignment payments must meet the requirements set forth in this section and be administered by the participant hospital in accordance with generally accepted accounting principles. In no event may the participant hospital receive any amounts from a CJR collaborator under a sharing arrangement that are not alignment payments.

• All gainsharing payments and alignment payments must be made through electronic funds transfers.

''Participation Agreements.'' We proposed a number of provisions that we believed should be set forth in the sharing arrangement or participation agreement (now termed ''collaborator agreement''). We have finalized and consolidated these provisions under § 510.500(c). Specifically, we are finalizing our proposal to require that each collaborator agreement must include and set forth in writing the following:

• The collaborator agreement must contain a description of the arrangement between the participant hospital and the CJR collaborator regarding gainsharing payments and alignment payments. This description must specify the following:

++ The parties to the sharing arrangement.

++ The date of the sharing arrangement.

++ The purpose and scope of the sharing arrangement; ++ The financial or economic terms of the sharing arrangement, including the frequency of payment, and the methodology and accounting formula for determining the amount of any gainsharing payment or alignment payment.

++ Safeguards to ensure that alignment payments are made solely for purposes related to sharing responsibility for funds needed to repay Medicare in the CJR model.

++ Plans regarding care redesign.

++ Changes in care coordination or delivery that is applied to the participant hospital or CJR collaborators or both.

++ A description of how success will be measured.

++ Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out changes to care under the model.

• The collaborator agreement must contain a requirement that the CJR collaborator and its employees and contractors must comply with the applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees) and all other applicable laws and regulations.

• The collaborator agreement must require the CJR collaborator to be in compliance with all Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the agreement.

• The collaborator agreement must require the CJR collaborator to have a compliance program that includes oversight of the collaborator agreement and compliance with the requirements of the CJR model.

• The collaborator agreement must set forth a specific methodology for accruing, calculating, and verifying the internal cost savings generated by the participant hospital based on the care redesign elements specifically associated with the particular CJR collaborator.

++ The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CJR collaborator or both.

++ The methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or business otherwise generated by, between, or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

++ The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book).

• The collaborator agreement must set forth the quality criteria established by the participant hospital that will be used in determining the gainsharing payment.

• The collaborator agreement must require the participant hospital to recoup gainsharing payments paid to CJR collaborators if gainsharing payments contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

• Any alignment payments made pursuant to a sharing arrangement may be made only to the participant hospital from the entity or individual with whom the participant hospital has signed a collaborator agreement containing a sharing arrangement.

• The collaborator agreement must require the CJR collaborator to comply with the beneficiary notice requirements specified in § 510.405, as applicable.

• Any internal cost savings or reconciliation payments that the participant hospital seeks to share through sharing arrangements must

meet the requirements set forth in this final rule and be administered by the participant hospital in accordance with GAAP. In no event may the participant hospital distribute any amounts pursuant to a sharing arrangement that are not comprised of either internal cost savings or a reconciliation payment, as those terms are defined in this final rule. All amounts determined to be internal cost savings by the participant hospital must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. In no case may internal cost savings reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

• Any alignment payments that the participant hospital receives through a sharing arrangement must meet the requirements set forth in this final rule and be administered by the participant hospital in accordance with GAAP.

• Sharing arrangements must not include any amounts that are not alignment payments or gainsharing payments.

• Each collaborator agreement —

++ Between the participant hospital and a CJR collaborator must obligate the CJR collaborator to provide the participant hospital and HHS access to the CJR collaborator's records, information, and data for purposes of monitoring and reporting and any other lawful purpose. Records, information, and data regarding the sharing arrangement must have sufficient detail to verify compliance with all material terms of the sharing arrangement and the terms of the CJR model;

++ Must require the participant hospital and the CJR collaborator to include in their compliance programs specific oversight of their collaborator agreements and compliance with the requirements of the CJR model;

++ If the participant hospital or CJR collaborator does not have a compliance program, each party must create one and incorporate the provisions described in this part in that program; and

++ Must require the board or other governing body of the participant hospital to have responsibility for overseeing the participant hospital's participation in the model, its arrangements with CJR Collaborators, its payment of Gainsharing Payments and receipt of Alignment Payments, and its use of beneficiary incentives in the CJR model.

• Collaborator agreements must require all CJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS (including CMS and OIG) and its designees for the purposes of operating the CJR model.

• Each collaborator agreement must require the CJR collaborator to permit site visits from CMS, and its designees, for purposes of evaluating the model.

''Documentation and Maintenance of Records.'' We are finalizing at § 510.500(d) our proposal with regard to certain documentation requirements, and we are finalizing at new § 510.500(e) our proposal regarding access to documents and record retention. Under § 510.500(d), we require the following documentation:

• Documentation of any collaborator agreement containing a sharing arrangement must be contemporaneous with the establishment of the arrangement.

• A participant hospital must maintain accurate current and historical lists of all CJR collaborators, including their names and addresses. The participant hospital must update the lists on at least a quarterly basis and publicly report the current and historical lists of CJR collaborators on a public-facing Web page on the participant hospital's Web site.

• The participant hospital and CJR collaborator must maintain contemporaneous documentation of the payment or receipt of any gainsharing payment or alignment payment. The documentation must identify at least the following: The nature of the payment (gainsharing payment or alignment payment); the identity of the parties making and receiving the payment; the date of the payment; the amount of the payment; and the date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

++ The participant hospital must keep records of the following:

++ Its process for determining and verifying the eligibility of CJR collaborators to participate in Medicare.

++ Information confirming the organizational readiness of the participant hospital to measure and track internal cost savings.

++ The participant hospital's plan to track internal cost savings.

++ Information on the accounting systems used to track internal cost savings.

++ A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

++ The participant hospital's plan to track gainsharing payments and alignment payments.

++ Whether the participant hospital recouped any gainsharing payments received by a CJR collaborator that contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

*''Access to Records and Record Retention.''* Section 510.500(e) finalizes our proposal regarding government access to books and records and document retention requirements. Specifically, § 510.500(e) requires that each participant hospital and CJR Collaborator, at a minimum, adhere to the following requirements:

• Provide to CMS, the OIG, and the Comptroller General or their designees scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality criteria, billings, lists of CJR collaborators, sharing arrangements, and distribution arrangements, and other documentation) sufficient to enable the audit, evaluation, inspection, or investigation of the individual's or entity's compliance with CJR requirements, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, or the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, or distribution payments.

• Maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

++ CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital or CJR collaborator at least 30 calendar days before the normal disposition date; or

++ There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CJR collaborator in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

We are finalizing without modification our proposal that OIG Authority is not limited or restricted by the provisions of the CJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CJR Collaborators, or any other person or entity or their records, data, or information, without limitation. In addition, we are finalizing without change our proposal that none of the provisions of the CJR model limits or restricts any other government authority permitted by law to audit,

evaluate, investigate, or inspect the participant hospital, CJR Collaborators, or any other person or entity or their records, data, or information, without limitation. These provisions are finalized at§ 510.510.

''Distribution Arrangements.'' As previously noted, we are finalizing our proposal with a modification to allow PGPs that are CJR collaborators to enter into distribution arrangements for the purposes of distributing all or a portion gainsharing payment with certain PGP members (practice collaboration agents). We note that we are not requiring the PGP to distribute all or a portion of a gainsharing payment to its member physicians and nonphysician practitioners. But where a PGP chooses to make such distributions, this final rule requires at new § 510.505 that all distribution arrangements must comply with all applicable laws and regulations and the following criteria:

- All distribution arrangements must be in writing and signed by the PGP and practice collaboration agent.
- Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.
- The distribution arrangement must require the practice collaboration agent to comply with the requirements set forth in this part.
- The opportunity to receive a distribution payment must not be conditioned directly or indirectly on the volume or value referrals or business otherwise generated by, between or among a participant hospital, the PGP, other CJR collaborators, any practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- Methodologies for determining distribution payments must not directly account for the volume or value of referrals, or business otherwise generated, by, between or among the participant hospital, CJR collaborators, other CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.
- A practice collaboration agent is eligible to receive a distribution payment only if the PGP billed for an item or service furnished by the practice collaboration agent to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP.
- Where a PGP receives a gainsharing payment from a participant hospital pursuant to a sharing arrangement, all monies contained in such a gainsharing payment must be shared only with the physician or nonphysician practitioners that are PGP members that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA, as that term is defined in section III.C.6. of the final rule, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment.
- The total amount of distribution payments for a calendar year paid to an individual physician or nonphysician practitioner who is a practice collaboration agent must not exceed a cap. The total amount of distribution payments for a calendar year paid to a practice collaboration agent must not exceed 50 percent of the total Medicare approved amounts under the Medicare Physician Fee Schedule (MPFS) for services billed by the PGP and furnished by the practice collaboration agent to the participant hospital's CJR beneficiaries during a CJR episode.
- With respect to the distribution of any gainsharing payment received by a PGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment.
- All distribution payments must be made through electronic funds transfers.
- The practice collaboration agents must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.
- The distribution arrangement must not—

++ Induce a practice collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

++ Reward the provision of items and services that are medically unnecessary.

- The PGP must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, the date and amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment.
- The PGP may not enter into a distribution arrangement with any member of the PGP that has a collaborator agreement in effect with a participant hospital.

b. Beneficiary Incentives Under the CJR Model

In the proposed rule, we stated our belief that the CJR model would incent participant hospitals to furnish services directly and otherwise coordinate services throughout the episode that lead to higher quality care for the beneficiary and lower episode spending. We proposed that one mechanism that may be useful to the participant hospital in achieving these goals would be the provision of certain items and services to the beneficiary during the episode of care. We also considered whether this policy on beneficiary incentives should extend to providers and suppliers, other than the participant hospital, that furnish services during the CJR episode of care. In the proposed rule, we stated our belief that hospitals are better suited than other providers and suppliers to provide beneficiary incentives. Thus, we proposed that participant hospitals could choose to provide certain in-kind patient engagement incentives to the beneficiary, subject to a number of conditions, including the following:

- The incentive must be provided by the participant hospital to the beneficiary during CJR episode of care.
- There must be a reasonable connection between the item or service and the beneficiary's medical care.
- The item or service must be a preventive care item or service or an item or service that advances a clinical goal for a CJR beneficiary, including the following: Increasing the beneficiary's engagement in the management of his or her own health care; adherence to a treatment or drug regimen; adherence to a follow-up care plan; reduction of readmissions and complications resulting from LEJR procedures; and management of chronic diseases and conditions that may be affected by the LEJR procedure.
- Items of technology must comply with certain safeguards, as discussed later in this section.
- The participant hospital must maintain contemporaneous documentation of the incentives provided to beneficiaries for a period of 10 years.
- The cost of the incentives must not be shifted to another federal health care program.

For example, under this proposal, participant hospitals could provide incentives such as post-surgical monitoring equipment to track patient weight and vital signs for post-surgical patients discharged directly to home, but they could not provide theater tickets, which would bear no reasonable connection to the patient's medical care.

Similarly, we proposed that participant hospitals might provide post-surgical monitoring equipment, but not broadly used technology that is more valuable to the beneficiary than equipment that is reasonably necessary for the patient's post-surgical care. In such circumstances, a reasonable inference arises that the technology would not be reasonably connected to the medical care of the patient. Among other things, this safeguard precludes incentives that might serve to induce beneficiaries inappropriately to receive other medical care that is not included in the episode.

In addition to the conditions previously noted, we proposed that participant hospitals would be required to maintain contemporaneous documentation of such items and services furnished whose value exceeds $10, including the date and identity of the beneficiary to whom the item or service was provided. We further proposed that the required documentation be maintained for a period of 10 years.

We also proposed that items and services involving technology provided to beneficiaries may not exceed $1,000 in retail value at the time of donation for any one beneficiary in any one CJR episode. Items of technology exceeding $50 in retail value at the time of donation must remain the property of the participant hospital and must be retrieved from the beneficiary at the end of the episode, with the documentation of the date of retrieval. In addition, we proposed that the amount and nature of the technology must be the minimum necessary to achieve the goals previously noted earlier in this section. Finally, we proposed that beneficiary incentives may not be tied to the receipt of services outside the episode of care and that the cost of the incentives cannot be shifted to a federal health care program. Our proposals regarding beneficiary incentives are consistent with the policies on beneficiary incentives in other CMS models, such as the BPCI initiative.

We sought comment on our proposal for beneficiary incentives under CJR. In addition to general comments on the proposal, we described our interest in comments on whether the $1000 retail value limit on technology items and services is necessary, reasonable, and appropriate. We also solicited comment on whether retrieving technology valued at more than $50 would be too burdensome and whether elimination of that requirement would prevent abuse. We also solicited comment on the documentation requirement for items and services furnished that exceed $10, or whether a different amount would be more appropriate and less burdensome. We welcomed comments on additional program integrity safeguards for these arrangements.

We proposed to set forth the CJR beneficiary incentives policies in § 510.505. However, in this final rule, the beneficiary incentives section has been renumbered to § 510.515. Thus, the following discussion incorporates the final beneficiary incentive policies under the new section number.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters expressed appreciation for CMS' proposal to permit beneficiary incentives to be provided by participant hospitals. The commenters agreed that CMS should establish certain conditions under which beneficiary incentives would be permitted, in order to ensure that beneficiary incentives are used solely to advance the goals of the CJR model for the beneficiary's care. These commenters further agreed that the beneficiary incentives should only be used when a beneficiary was in a CJR episode.

Several commenters expressed concern about the use of beneficiary incentives in a payment model such as the CJR model that commonly includes a substantial period of PAC services which may be furnished by different provider types during the episode, as opposed to the more traditional use of beneficiary incentives in a wellness environment where such incentives are related to prevention and primary care. The commenters urged CMS to maintain the requirement of a reasonable connection between the service and a beneficiary's medical care and that the service advance a meaningful clinical goal for the beneficiary under the CJR model. The commenters suggested that CMS take two further actions to strengthen the protections against hospitals' misuse of beneficiary incentives to influence the beneficiary's choice of providers and types of care. First, they recommended that CMS include strong and specific language prohibiting the formal or informal use of incentives as a way to steer beneficiaries toward a certain provider or type of services. Second, they urged CMS to additionally require that hospitals offer beneficiary incentives in the same way to all patients and that the hospital make their beneficiary incentive policy publicly available.

*Response:* We appreciate the support of the commenters for our proposal to allow beneficiary incentives under certain conditions in the CJR model, including requirements related to advancing a clinical goal and use of the incentive during the episode. We wish to clarify that beneficiary incentives should be reasonably connected to medical care that is provided during an episode, which is consistent with our proposal that beneficiary incentives not be tied to the receipt of services outside the episode of care. We note that the clinical goals of the model that may be advanced through beneficiary incentives include beneficiary adherence to drug regimens, beneficiary adherence to a care plan, reduction of readmissions and complications resulting from LEJR procedures, and management of chronic diseases and conditions that may be affected by the LEJR procedure. We further note that this final rule defines an episode to include services for chronic diseases and conditions that may be affected by the LEJR procedure or post-surgical care (see section III.B.2.b. of this final rule). To the extent that services for these chronic conditions are included in CJR model episodes, we believe it is appropriate to permit beneficiary incentives to manage these chronic diseases and conditions during the episode. For example, we would consider a beneficiary incentive to advance the clinical goals of the CJR model and to be connected to medical care provided to the beneficiary during the episode if the incentive is related to a chronic condition, such as diabetes or congestive heart failure, that may be affected by the LEJR procedure or post-surgical care and is included in the LEJR episode.

We appreciate the concerns of some commenters about the potential misuse of beneficiary incentives to steer beneficiaries toward a certain type of provider or type of services. We believe that requiring beneficiary incentives to be provided only by a participant hospital partially reduces the likelihood that such an incentive would be used to steer a beneficiary toward a specific PAC provider or type of PAC services. We are accepting the commenters' suggestion to add a requirement that beneficiary incentives must not be tied to the receipt of items or services from a particular provider or supplier. We believe this requirement, which will appear at new § 510.515(a)(5), will further reduce the potential for use of beneficiary incentives to steer a beneficiary toward a specific provider or supplier.

While we agree with the commenters who recommended that we explicitly prohibit the use of beneficiary incentives to steer a beneficiary toward a certain type of provider or types of services, we do not believe that hospitals should be required to offer the incentives in the same way to all

beneficiaries in the model or to make their policies regarding beneficiary incentives publicly available. Hospitals may want to offer beneficiary incentives to those CJR model beneficiaries with the greatest need, even if CJR model beneficiaries have similar clinical goals. In addition, we do not believe it would be appropriate to require hospitals to make their policies regarding beneficiary incentives publicly available because, as later discussed in this section, we do not believe that the availability of beneficiary incentives should be advertised or marketed to beneficiaries.

We believe that certain aspects of our proposal on beneficiary incentives will help to protect the program and beneficiaries from misuse of such incentives, including the requirements that only a hospital may provide patient incentives, that the incentives must be furnished during an episode of care, and that the item or service is either a preventive care item or service or advances a clinical goal for a CJR beneficiary. Accordingly, we are finalizing the conditions that we proposed in § 510.515(a)(1) and (2), but with some modification. First, we wish to clarify that the items and services may be provided by the hospital through an agent who is under the hospital's direction and control. We note that if a reasonable beneficiary would perceive the item or service as being from the agent rather than the hospital, we would not consider the incentive to have been provided by the hospital. Second, as previously noted, we are clarifying in § 510.515(a)(2) that the items and services must be reasonably connected to medical care provided to a beneficiary during an episode. We are separately incorporating the requirement that the item or service be a preventive care item or service or advance a clinical goal for a beneficiary in a CJR episode in new § 510.515(a)(3). In addition, we are also adding a new § 510.515(a)(4) to set forth the proposed requirement that the item or service must not be tied to the receipt of services outside of the episode of care. To clarify, our proposed requirement that the item or service must not be tied to the receipt of services outside of the episode of care should have also referred to the receipt of items outside of the episode of care. Thus, the new § 510.515(a)(4) requires that the item or service must not be tied to the receipt of items or services outside of the episode of care.

*Comment:* Some commenters recognized that beneficiary incentives have potential value to model beneficiaries, especially the use of new technology that will help beneficiaries better monitor their health. However, they pointed out that the incentives could be a financial burden on hospitals when model beneficiaries can choose any provider for their care. They added that beneficiary incentives would lead to a cost to the hospital, with no guarantee of quality improvement. The commenters expressed concerns that small benefits due to beneficiary incentives would be outweighed by their costs to hospitals and the additional cost to CMS of monitoring their use.

*Response:* We recognize that the provision of beneficiary incentives may create some additional costs and administrative burden for participant hospitals. However, we believe that it is important to provide participant hospitals with the option to furnish beneficiary incentives in a manner that will not result in patient steering or other abuse. The participant hospitals are not required to offer beneficiary incentives. Thus, hospitals are free to determine whether it will be useful or feasible to provide beneficiary incentives in accordance with the terms of this final rule.

*Comment:* Several commenters recommended that CMS not permit marketing of beneficiary incentives, similar to the existing requirements for beneficiary incentives in Medicare Advantage plans. The commenters stated that this additional condition would provide further protection against the potential for beneficiary incentives being used to steer beneficiaries to certain providers.

*Response:* We agree that beneficiary incentives should not be marketed to beneficiaries, because this could unduly influence their selection of a provider or type of service. As discussed previously, we are incorporating the requirement that beneficiary incentives must not be tied to the receipt of items or services from a particular provider or supplier. We believe it would be difficult to meet this requirement if the availability of the items or services was advertised or promoted except in the case where a CJR beneficiary is only made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them. For example, when a participant hospital initiates post-discharge planning for a CJR beneficiary with a chronic health condition, the participant hospital could discuss providing the beneficiary with an electronic tablet for home use to track certain measurements and health information and to transmit this information periodically to the beneficiary's physician to aid in post-operative recovery and management of the chronic health condition. We are including this condition in new § 510.515(a)(6).

*Comment:* Many commenters opposed the proposed requirements that hospitals maintain contemporaneous documentation of beneficiary incentive items and services whose value exceeds $10. The commenters recommended that CMS increase the threshold to $50, $100, or a higher value in order to minimize unnecessary administrative burden. Some commenters also suggested that CMS exempt beneficiary incentives from the 10-year documentation requirement to further reduce burden.

*Response:* We appreciate the perspectives of the commenters on our proposed requirements for contemporaneous documentation of all beneficiary incentive items and services furnished whose value exceeds $10, including the date and the identity of the beneficiary to whom the item or service was provided. We note that, like the $1,000 limit for beneficiary incentives involving technology items and services, our proposed documentation threshold of $10 was intended to represent the retail value of the item or service. We proposed a $10 retail value threshold for documentation because we recognized that a beneficiary could receive many incentives that are each of low dollar value but in the aggregate constitute an excessively high value to the beneficiary. We believe is important to maintain the documentation threshold at a modest level for all beneficiary incentives in order to monitor compliance with the requirements for providing these items and services. We believed that the $10 threshold represented an appropriate balance between the benefits of beneficiary incentives and burden of the documentation requirement.

The commenters did not provide specific examples of items and services that would be commonly furnished as beneficiary incentives such that the cumulative documentation burden on the hospital for CJR model beneficiaries would outweigh the potential benefit to the beneficiary of the item or services. However, after considering the comments, we believe a higher retail value threshold of $25 would strike the appropriate balance between beneficiary and program protections and participant hospital administrative burden. This higher threshold will eliminate the documentation burden for some beneficiary incentives. Therefore, at § 510.515(c)(1), we are finalizing our proposed requirement that participant

hospitals must maintain a contemporaneous list of items and services furnished as beneficiary incentives, including the date the incentive was provided and the identity of the beneficiary to whom it was provided. We specify in that section that this obligation applies only to incentives that exceed $25 in retail value. Under new § 510.515(c)(2), we set forth the requirement that the participant hospital must retain the required documentation in accordance with new § 510.515(e), which we have added to establish our proposed documentation and maintenance of records provision for beneficiary incentives.

We recognize that the 10-year retention requirement imposes some administrative burden, but we note that such a 10-year requirement is commonly used in Medicare. We do not believe it would be appropriate to reduce that document retention period for beneficiary incentives furnished under this model.

*Comment:* Several commenters provided their perspectives on the proposed $50 retail value threshold for items of technology that must remain the property of the participant hospital and be retrieved at the end of the episode. Some commenters recommended that CMS increase this threshold to $100 or $500. Many commenters expressed particular concern about the proposed requirement to retrieve technology from a beneficiary following the end of the episode because they believed it could be impossible to locate some beneficiaries and/or retrieve the technology from them in some cases. These commenters requested that CMS waive this requirement for hospital demonstration of a good faith effort to retrieve the technology. A number of commenters requested that CMS eliminate the requirement to maintain documentation of the date of retrieval. The commenters generally expressed concerns about the legal, compliance, documentation, and administrative resources associated with the proposed requirements for items of technology provided as beneficiary incentives. While no commenters objected to the proposed retail value limit of $1,000 on items and services of technology, a commenter questioned the meaning of this limit. The commenter inquired whether a hospital could be paid by CMS for the incentive and questioned the use of the term ''donate'' in the proposed rule in the discussion of the ''retail value at the time of donation'' of items involving technology.

*Response:* The commenters did not provide specific information about the types of technology that they believe should remain the property of the beneficiary at the end of episode. However, we believe that a higher threshold than the one we proposed for items of technology that must remain the property of the participant hospital may result in useful beneficiary incentives that, in light of other regulatory safeguards, would not pose an undue risk of patient steering or other abuse. One important safeguard is the inability of a hospital to advertise or promote the availability of the technology. In addition, we are finalizing our proposed safeguard requiring that items and services involving technology must be the minimum necessary to advance a clinical goal for a CJR beneficiary (as defined in § 510.515(b)). We note that we are finalizing the term ''advance a clinical goal'' in this provision, rather than our proposed language (''achieve a clinical goal''), for consistency with § 510.515(b), which identifies the clinical goals that may be ''advanced'' through beneficiary incentives. Accordingly, in light of these safeguards, we believe it is appropriate to raise the technology retrieval threshold to a retail value of $100 which, for example, would allow some types of electronic tablets that could be furnished to a beneficiary for health monitoring during a CJR model episode to remain the property of the beneficiary following the end of the episode.

We understand the administrative burden on hospitals that tracking and retrieval requires, but believe that a higher retrieval threshold is not warranted. For example, given that the majority of CJR episodes will be elective THA or TKA procedures, we believe it would be inappropriate for participant hospitals to furnish items of technology with a retail value of over $100 for beneficiaries' permanent use because the high value of these items could unduly influence the beneficiary to receive services from the hospital, particularly services outside of the CJR episode of care. We do not believe the administrative burden of retrieving items involving technology with a retail value in excess of $100 outweighs the program integrity benefits of retrieval. Therefore, we are finalizing § 510.515(d)(3) to reflect the $100 retail value threshold for retrieval of items of technology.

We decline to exempt items of technology and their retrieval date from the documentation requirements. We believe that documentation is important to ensure that the provision of items of technology is in compliance with program requirements and is not used by a participant hospital to steer beneficiaries toward one provider or type of service or to engage in other abusive conduct. We stress that hospitals must carefully and completely document all of their attempts to retrieve from a beneficiary at the end of an episode items of technology whose retail value exceeds $100, regardless of whether the hospital is ultimately successful in retrieving the technology. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. These policies are set forth in § 510.515(d)(3)(ii).

Hospitals will not be reimbursed by CMS for the cost of items and services furnished to CJR model beneficiaries as beneficiary incentives. Participant hospitals may choose to provide in-kind patient engagement incentives to beneficiaries in CJR model episodes in accordance with the CJR regulations. Items and services of technology furnished as beneficiary incentives may not exceed $1,000 in retail value at the time they are furnished to any one beneficiary in a single CJR model episode.

Finally, we acknowledge that, in light of our proposal to require retrieval of certain items of technology, our use of the word ''donate'' was imprecise. We intended to refer to the retail value of technology at this time it was ''furnished'' to a model beneficiary.

*Comment:* Several commenters recommended that CMS allow other types of beneficiary incentives, including waivers of Part B coinsurance amounts and opportunities for participant hospitals to share reconciliation payments with model beneficiaries when actual episode spending is less than the target price.

*Response:* We appreciate these suggestions for additional beneficiary incentives. However, we are limiting our policies to the incentives as proposed and subsequently modified and finalized in this final rule. We do not believe that waivers of the Part B coinsurance amounts are necessary for the model test to advance clinical goals for model beneficiaries in view of the typical services furnished to beneficiaries in LEJR episodes and the aggregate modest associated coinsurance amounts. We also do not believe that sharing savings would be appropriate as such a policy could unduly influence a beneficiary's choice of types of care.

*Comment:* Several commenters recommended that CMS or the OIG should establish a dedicated email address or other communication portal

for questions about beneficiary incentives, so that participant hospitals could receive informal compliance advice in order to ensure that their use of beneficiary incentives in the CJR model meets the required conditions. Other commenters requested specific guidance on certain items with respect to the beneficiary incentives conditions, including post-surgical intermittent pneumatic compression devices, the determination of retail prices, supportive services that are in short supply or inadequate such as hot meal delivery, home preparation for a beneficiary who left home urgently, or enhanced homemaker or personal care aide services.

*Response:* We appreciate the interest of the commenters in understanding the conditions under which beneficiary incentives can be furnished under the CJR model. We believe that this final rule provides sufficient guidance on the requirements for beneficiary incentives under the model. Only beneficiary incentives that meet all of these requirements are permitted under this model. We will not provide informal compliance advice or provide additional advisory information about specific items or services or other definitions and terms in this final rule. Participant hospitals should review the regulations for the conditions and requirements to make sure their plans for beneficiary incentives comply with all of the requirements and conditions set forth in this final rule and any other applicable law. Any guidance from OIG regarding its authorities would be provided outside the scope of this rulemaking.

*Comment:* Several commenters recommended that CMS prohibit hospitals from shifting the cost of the incentives to government programs generally, including state health care programs, not only federal health care programs. Other commenters suggested that CMS further extend the cost-shifting prohibition to commercial programs.

*Response:* We intend to prohibit cost shifting to a ''Federal health care program,'' as defined at 42 U.S.C. 1320a–7b(f) (section 1128–7b(f) of the Act), which encompasses the following broad array of government health care programs:

- Any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code [5 U.S.C. 8901 *et seq.*]); or
- Any state health care program, as defined in section 1128(h) [42 U.S.C. 1320a-7(h)], which includes the following:
- A state plan approved under title XIX [42 U.S.C. 1396 *et seq.*].
- Any program receiving funds under title V [42 U.S.C. 701 *et seq.*] or from an allotment to a state under such title.
- Any program receiving funds under subtitle 1 of title XX [42 U.S.C. 1397 *et seq.*] or from an allotment to a State under such subtitle.
- A state child health plan approved under title XXI [42 U.S.C. 1397aa *et seq.*].

We do not believe it would be appropriate to expand this cost-shifting prohibition to other government programs generally or to commercial programs. We question whether we have the authority to expand the cost-shifting prohibition to commercial payers. Moreover, we believe it would be very difficult to enforce such a provision in a meaningful manner.

We are finalizing this proposed condition in § 510.515(a)(7).

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal for beneficiary incentives under the CJR model, with certain modifications. We are clarifying at § 510.515(a)(1) that the items and services may be provided by the hospital through an agent who is under the hospital's direction and control. We note that if a reasonable beneficiary would perceive the item or service as being from the agent rather than the hospital, we would not consider the incentive to have been provided by the hospital. As previously noted, we are clarifying in § 510.515(a)(2) that the items and services must be reasonably connected to medical care provided to a beneficiary ''during an episode.'' We are separately incorporating at § 510.515(a)(3) the proposed requirement that the item or service be a preventive care item or service or advance a clinical goal for a beneficiary in a CJR episode. In addition, we are also adding a new paragraph(a)(4) at § 510.515 to set forth the proposed requirement that the item or service must not be tied to the receipt of items or services outside of the episode of care. At the suggestion of the commenters, we are adding new provisions to require that—(1) The item or service may not be tied to receipt of items or services from a particular provider or supplier; and (2) the availability of the items or services must not be advertised or promoted, except that a beneficiary may be made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them. These conditions appear at § 510.515(a)(5) and (6). We are finalizing the proposed requirement in § 510.515(a)(7) that the cost of the items or services must not be shifted to another federal health care program.

We are also finalizing § 510.515(b) regarding the goals of the CJR model. We note that § 510.515(b)(2) is being finalized with modification to avoid redundancy. The provision will refer to beneficiary adherence to ''a care plan,'' rather than ''a follow-up care plan or care,'' since a care plan would include follow up and other care. In addition, we are finalizing the proposed documentation requirement for beneficiary incentives with certain changes; it will apply only to those items and services furnished as beneficiary incentives whose retail value exceeds $25, and it requires contemporaneous documentation to be retained for 10 years. As no commenters objected to the proposed limit of $1,000 in retail value for items and services involving technology provided to any one beneficiary in any one CJR episode, we are finalizing this requirement under § 510.515(d)(1). We are also finalizing in revised § 510.515(d)(2) the proposed condition that the items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal for a CJR beneficiary. Moreover, we are modifying the requirement that items of technology furnished as beneficiary incentives remain the property of the participant hospital and be retrieved from the beneficiary at the end of the model to apply only to those items of technology that exceed $100 in retail value, and finalizing these requirements under § 510.515(d)(3) and paragraph (d)(3)(i). Under § 510.515(d)(3)(ii), documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement. Finally, we are adding new § 510.515(e) to establish the proposed documentation and record retention provision for beneficiary incentives furnished under the CJR model.

The final beneficiary incentive policies are set forth in § 510.515.

11. Waivers of Medicare Program Rules

a. Overview

In the proposed rule, we stated our belief that it may be necessary and appropriate to provide additional flexibilities to hospitals participating in CJR, as well as other providers that furnish services to beneficiaries in CJR episodes. The purpose of such flexibilities would be to increase LEJR episode quality and decrease episode

spending or provider and supplier internal costs, or both, and to provide better, more coordinated care for beneficiaries and improved financial efficiencies for Medicare, providers, and beneficiaries. These possible additional flexibilities could include use of our waiver authority under section 1115A of the Act, which provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

As we have stated elsewhere in sections I.A. and III.A.3 of this final rule, our previous and current efforts in testing episode payment models have led us to believe that models where entities bear financial responsibility for total Medicare spending for episodes of care hold the potential to incentivize the most substantial improvements in episode quality and efficiency. As discussed in section III.C. of this final rule, we proposed that hospitals participating in this model be eligible for reconciliation payments based on improved performance starting in performance year 1, and we would phase-in repayment responsibility for excess episode spending starting in performance year 2. In the proposed rule, we stated our belief that where participant hospitals bear repayment responsibility for excess episode spending that surpasses the target price while high quality care is valued, they will have an increased incentive to coordinate care furnished by the hospital and other providers and suppliers throughout the episode to improve the quality and efficiency of care. With these incentives present, there may be a reduced likelihood of over-utilization of services that could otherwise result from waivers of Medicare program rules. Given these circumstances, waivers of certain program rules for providers and suppliers furnishing services to CJR beneficiaries may be appropriate to offer more flexibility than under existing Medicare rules for such providers and suppliers, so that they may provide appropriate, efficient care for beneficiaries. An example of such a program rule that could be waived to potentially allow more efficient LEJR episode care would be the 3-day inpatient hospital stay requirement prior to a covered SNF stay for beneficiaries who could appropriately be discharged to a SNF after less than a 3-day inpatient hospital stay.

In addition, in the proposed rule we stated our belief that waivers of certain Medicare program rules are necessary to make reconciliation payments to or recoup payments from participant hospitals as a result of the NPRA for each performance year as discussed in section III.C.6.a. of this final rule, as well as to exclude beneficiary cost-sharing from these reconciliation payments or repayments.

We welcomed comments on possible waivers under section 1115A of the Act of certain Medicare program rules that surpass those specifically discussed in the proposed rule that might be necessary to test this model. In the proposed rule, we stated that we would consider the comments that are received during the public comment period and our early model implementation experience and may make future proposals regarding program rule waivers during the course of the model test. We noted that we were especially interested in comments explaining how such waivers could provide providers and suppliers with additional ways to increase quality of care and reduce unnecessary episode spending, but that could be appropriately used in the context of CJR where participant hospitals bear full responsibility for total episode spending by performance year 3. We were also interested in receiving comments regarding the timing and manner in which such waivers, were they to be offered, would be implemented. For example, would it be necessary and appropriate to offer program waivers early in the model to allow providers and suppliers adequate time to adjust their care coordination strategies to implement changes permitted by the waivers, despite there being no full repayment responsibility for excess episode spending until performance year 3? What program integrity and beneficiary protection risks could be introduced by waivers of the program rules described later in this section of this final rule and how could we mitigate those risks? What other issues should be considered when making use of waiver authority with respect to program rules? What operational issues do CMS and providers and suppliers furnishing services to beneficiaries in the model need to consider and what processes would need to be in place to implement these alternative program policies? What implications would there be for provider and supplier infrastructure, including IT and other systems and processes? What provider education would be needed? We noted that any waivers included in a final rule would be offered to participant hospitals, but depending on the specifics of each waiver, might be applied to services furnished by providers and suppliers other than the hospital. Where that is the case, we sought input on how we may best educate and disseminate information using methods effective in reaching providers and suppliers. Additionally, we sought comment on how we would appropriately and accurately track the use of waivers by providers and suppliers other than participant hospitals.

Specific program rules for which we proposed waivers under the CJR model to support provider and supplier efforts to increase quality and decrease episode spending and for which we invited comments are included in the sections that follow. We proposed that these waivers of program rules would apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under a waiver, even if the episode is later canceled as described in section III.B.3.b of this final rule. If a service is found to have been billed and paid by Medicare under circumstances only allowed by a program rule waiver for a beneficiary not in the CJR model at the time a service under a waiver was furnished, CMS would recoup payment for that service from the provider or supplier who was paid, and require that provider or supplier to repay the beneficiary for any coinsurance previously collected.

The following is a summary of the comments received and our response.

*Comment:* Many commenters commended CMS for proposing that the waivers of Medicare program rules would apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under a waiver, even if the episode is later canceled. The commenters believe that CMS addressed an important ambiguity that exists in the use of similar waivers under BPCI, given that both BPCI and the proposed CJR model are retrospective payment models where payment is made to Medicare providers and suppliers throughout the episode. Several commenters requested clarification of the proposal regarding its applicability to beneficiaries whose change in coverage at some point in the episode following provision of a service under a waiver leads to the beneficiary's care ultimately being excluded from the model. They provided examples such as a beneficiary who enrolled in a Medicare Advantage plan or whose Medicare eligibility changed to the ESRD benefit at some point during an

episode after a service permitted by a CJR model program rule waiver was furnished. These commenters argued that CMS should treat situations of changes in coverage that exclude beneficiaries' care from the CJR model the same as CMS proposed to treat episode cancellations. That is, the commenters recommended that the waivers should apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under the waiver, even if the beneficiary's care is later excluded from the model due to a change in the beneficiary's coverage during the episode.

*Response:* We agree with the commenters that it would be appropriate to treat the applicability of program rule waivers to beneficiaries whose care is later excluded from the model due to changes in beneficiary coverage in the same way as we proposed to treat episode cancellations, because based on beneficiary coverage at the time services are furnished under the waiver, the beneficiary's care was included in the model. The ultimate exclusion of the beneficiary's care from the model would not be decided until a later point in the episode when a change in the beneficiary's coverage would result in cancellation of the episode. As discussed in the proposed rule in regard to episode cancellation, we believe it would be appropriate to cancel the episode when a beneficiary's status changes during the episode such that they no longer meet the criteria for inclusion. Therefore, if a beneficiary's coverage or circumstances change during the episode such that they no longer meet the criteria for inclusion, as would occur in the examples provided by the commenters, the episode would be canceled. Thus, under our proposal, waivers of Medicare program rules would apply to the care of beneficiaries who are in CJR episodes at the time a service is furnished to a beneficiary under a waiver even if the episode is later canceled, which includes circumstances where the beneficiary's care is ultimately excluded from the CJR model due to a change in the beneficiary's coverage during the episode. We believe it is important to structure the CJR Medicare program rule waivers in this way so that later episode cancellations that could not be known or anticipated by providers or beneficiaries at the time services are furnished under a waiver, would not result in unexpected provider or beneficiary financial liability.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, without modification, that waivers of Medicare program rules would apply to the care of beneficiaries who are in CJR model episodes at the time the service is furnished to the beneficiary under the waiver, even if the episode is later canceled. This policy would include circumstances where a beneficiary's care is ultimately excluded from the CJR model due to a change in the beneficiary's coverage during the episode. As discussed in the proposed rule, if a service is found to have been billed and paid by Medicare under circumstances only allowed by a program rule waiver for a beneficiary not in the CJR model at the time a service under a waiver was furnished, CMS will recoup payment for that service from the provider or supplier who was paid. However, for this situation we are not finalizing our proposal to require that providers or suppliers repay the beneficiary for any coinsurance previously collected. We may consider other approaches to handling these types of issues in the future.

In the proposed rule, we also generally sought comment on any additional Medicare program rules that it may be necessary to waive using our authority under section 1115A of the Act in order to effectively test the CJR model that we could consider in the context of our early model implementation experience to inform any future proposals we may make.

The following is a summary of the comments received and our response.

*Comment:* Many commenters requested that CMS consider additional program rule waivers for the CJR model that surpass those specifically proposed for the model. The commenters provided information about how those waivers could be used to enhance the efficiency and quality of care for CJR model beneficiaries, allowing the widest variety of interested and well-prepared providers and suppliers to partner with hospitals in care redesign for LEJR episodes. Some suggested waivers were specific to payment, such as providing ''per diem'' payment for IRFs, changing payment under the IPPS PAC transfer policy, and eliminating the Part B therapy caps. Several commenters recommended that CMS waive the Part B copayments for CJR model beneficiaries. Requests for waivers specific to the rules governing certain types of providers and suppliers included waivers of the IRF 60-percent rule and 3-hour therapy rule that specifies the particular models of therapy permitted, waiver of the physician supervision rules for certified registered nurse anesthetists, and waiver of the requirement for physicians to certify home health services to allow NPPs to perform this task. Waivers of CMS review policies for CJR collaborators were requested by some commenters, including waivers of manual medical review policies and prepayment and postpayment reviews. Many commenters requested waivers of the hospital discharge planning requirements in order to allow hospitals to share lists of only those PAC providers collaborating on the model with the participant hospital, as well as waivers to allow home health providers to furnish pre-surgical counseling and visits and to assist with discharge planning and care transitions for beneficiaries. Finally, several commenters suggested that CMS provide very general waivers that would waive all policies that may impact a PAC provider's ability to admit a CJR beneficiary or be paid for services furnished to them or, even more broadly, waivers of all the relevant regulations that impede the ability of hospitals to effectively coordinate and manage a patient's care.

*Response:* We appreciate the information provided by the commenters and, as discussed in the proposed rule, we will consider the comments we received during the public comment period and our early model implementation experience and may make future proposals regarding program rule waivers during the course of the model test.

We refer readers to section III.F.2. of this final rule for a discussion of the discharge planning requirements under the CJR model.

*Final Decision:* We address the Medicare programmatic waivers we proposed in the proposed rule in the following sections. We decline at this time to waive any additional Medicare programmatic requirements. We will review the information provided by the commenters and our early model experience and may consider waiving additional requirements during the course of the model test.

b. Post-Discharge Home Visits

In the proposed rule, we stated our expectation that the broadly defined LEJR episodes with duration of 90 days following hospital discharge as we proposed in section III.B. of this final rule would result in participant hospitals redesigning care by increasing care coordination and management of beneficiaries following surgery. This would require participant hospitals to pay close attention to any underlying medical conditions that could be affected by the anchor hospitalization

and improving coordination of care across care settings and providers. Beneficiaries may have substantial mobility limitations during LEJR episodes following discharge to their home or place of residence that may interfere with their ability to travel easily to physicians' offices or other health care settings. Adopting new strategies to increase beneficiary adherence to and engagement with recommended treatment and follow-up care following discharge from the hospital or PAC setting would also be important to high quality episode care. Scientific evidence exists [48] to support the use of home nursing visits among Medicare beneficiaries in improving care coordination following hospital discharge. In addition, in the proposed rule, we stated our belief that the financial incentives in this episode payment model would encourage hospitals to closely examine the most appropriate PAC settings for beneficiaries so that the clinically appropriate setting of the lowest acuity is recommended following discharge from the anchor hospitalization. We discussed our expectation that all these considerations would lead to greater interest on the part of hospitals and other providers and suppliers caring for CJR beneficiaries in furnishing services to beneficiaries in their home or place of residence. Such services could include visits by licensed clinicians other than physicians and nonphysician practitioners.

In order for Medicare to pay for home health services, a beneficiary must be determined to be ''home-bound''. Specifically, sections 1835(a) and 1814(a) of the Act require that a physician certify (and recertify) that in the case of home health services under the Medicare home health benefit, such services are or were required because the individual is or was ''confined to the home'' and needs or needed skilled nursing care on an intermittent basis, or physical or speech therapy or has or had a continuing need for occupational therapy. A beneficiary is considered to be confined to the home if the beneficiary has a condition, due to an illness or injury, that restricts his or her ability to leave home except with the assistance of another individual or the aid of a supportive device (that is, crutches, a cane, a wheelchair or a walker) or if the beneficiary has a condition such that leaving his or her home is medically contraindicated. While a beneficiary does not have to be bedridden to be considered confined to the home, the condition of the beneficiary must be such that there exists a normal inability to leave home and leaving home requires a considerable and taxing effort by the beneficiary. Absent this condition, it would be expected that the beneficiary could typically get the same services in an outpatient or other setting. Thus, the homebound requirement provides a way to help differentiate between patients that require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting. Additional information regarding the homebound requirement is available in the Medicare Benefit Manual (Pub 100–02); Chapter 7, ''Home Health Services'' Section 30.1.1, ''Patient Confined to the Home''.

We considered whether a waiver of the homebound requirement would be appropriate under the CJR model, particularly beginning in performance year 2, where hospitals begin to bear repayment responsibility for excess episode spending. Waiving the homebound requirement would allow additional beneficiaries to receive home health care services in their home or place of residence. As previously discussed, physician certification that a beneficiary meets the homebound requirement is a prerequisite for Medicare coverage of home health services, and waiving the homebound requirement could result in lower episode spending in some instances. For example, if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered homebound, the beneficiary may avoid a hospital readmission. All other requirements for the Medicare home health benefit would remain unchanged. Thus, under such a waiver, only beneficiaries who otherwise meet all program requirements to receive home health services would be eligible for coverage of home health services without being homebound.

However, we did not propose to waive the homebound requirement under CJR for several reasons. Based on the typical clinical course of beneficiaries after LEJR procedures, we stated our belief that many beneficiaries would meet the homebound requirement for home health services immediately following discharge from the anchor hospitalization or following discharge to their home or place of residence from a SNF that furnished PAC services immediately following the hospital discharge, so they could receive medically necessary home health services under existing program rules. Home health episodes are 60 days in duration, and payment adjustments are made for beneficiaries who require only a few visits during the home health episode or who are discharged during the home health episode. For those CJR beneficiaries who could benefit from home visits by a licensed clinician for purposes of assessment and monitoring of their clinical condition, care coordination, and improving adherence with treatment but who are not homebound, we did not believe that paying for these visits as home health services under Medicare is necessary or appropriate, especially given that Medicare payments for home health services are set based on the clinical care furnished to beneficiaries who are truly homebound. Finally, in other CMS episode payment models, such as BPCI, we have not waived the homebound requirement for home health services.

The following is a summary of the comments received and our response.

*Comment:* Several commenters requested that CMS waive the homebound requirement for the entire 90-day period of time included in the LEJR episode following discharge from the anchor hospitalization. They recommended that such a waiver would allow home health services to be furnished whenever medically necessary throughout the entire length of the CJR model episode, leading to improvements in continuity and care coordination and serving as a natural extension of home health care furnished by a HHA that many beneficiaries would likely receive when homebound at an earlier time in the episode.

*Response:* While we appreciate the commenters' requests that we waive the homebound requirement for home health services, we disagree that waiving the homebound requirement is necessary for the test of the CJR model. As discussed in the proposed rule, we proposed to waive the ''incident to'' direct physician supervision requirement for post-discharge home visits in order to allow clinical staff to furnish post-discharge home visits to CJR model beneficiaries who do not meet the requirements for home health services. We believe that this would allow the home visits for non-homebound CJR model beneficiaries that we believe are necessary for testing the model. As we discussed in the proposed rule, we believe many CJR beneficiaries should qualify for home health services under the existing program rules, especially immediately after discharge from the hospital or discharge from an institutional setting such as a SNF to their residence.

[48] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS. Comprehensive discharge planning and home follow up of hospitalized elders: A randomized clinical trial. JAMA. 1999: 281(7): 613 620. doi:10/1001/jama.281.7.6136.

Furthermore, as a retrospective payment model, all providers and suppliers are paid for services furnished to model beneficiaries at their usual rates, and program payments for home health services are set based on the needs of Medicare beneficiaries who are truly homebound. The resources required to care for homebound beneficiaries in the home are likely greater than those required for CJR beneficiaries who are not homebound. Therefore, waiving the homebound requirement would lead to inappropriate payment for post-discharge home visits to CJR model beneficiaries and could result in increased CJR episode actual spending, which is counter to the goals of the CJR model.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, without modification, to maintain the existing Medicare requirements for home health services, including the requirement that the beneficiary be homebound, when home health services are furnished to CJR model beneficiaries.

In the proposed rule, we noted that in BPCI, we have provided a waiver of the ''incident to'' direct physician supervision requirement in order to allow a physician or NPP participating in care redesign under a participating BPCI provider to bill for services furnished to a beneficiary who does not qualify for Medicare coverage of home health services as set forth under § 409.42 where the services are furnished in the beneficiary's home during the episode after the beneficiary's discharge from an acute care hospital. The ''incident to'' direct physician supervision requirement is set forth at § 410.26(b)(5), in which services and supplies furnished ''incident to'' the service of a physician or other practitioner must be provided under the direct supervision (as defined at § 410.32(b)(3)(ii)) of a physician or other practitioner.

In BPCI, the waiver is available only for services that are furnished by licensed clinical staff under the general supervision (as defined at § 410.32(b)(3)(i)) of a physician (or other practitioner), as long as the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner), or of the same entity that employs or contracts with the physician (or other practitioner), and while the services may be furnished by licensed clinical staff they must be billed by the physician (or other practitioner) in accordance with CMS instructions using a HCPCS G-code created by CMS specifically for the BPCI initiative. As discussed in section III.B. of this final rule, participants in the BPCI initiative are permitted to select the duration of an episode as 30 days, 60 days or 90 days. In the case of the ''incident to'' direct physician supervision waiver under BPCI, the waiver allows physicians and NPPs to furnish the services not more than once in a 30-day episode, not more than twice in a 60-day episode, and not more than three times in a 90-day episode. All other Medicare coverage and payment criteria must be met.

For the CJR model, we proposed to waive the ''incident to'' direct physician supervision requirement set forth at § 410.26(b)(5), to allow a CJR beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The waiver would not apply for beneficiaries who would qualify for home health services under the Medicare program, as set forth under § 409.42. Therefore these visits could not be billed for such beneficiaries. We proposed to allow licensed clinicians, such as nurses, either employed by a hospital or not, to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital. We proposed to allow services furnished under such a waiver to be billed under the MPFS by the physician or NPP or by the hospital to which the supervising physician has reassigned his or her benefits. In the latter scenario, we noted that the post-discharge home visit services would not be ''hospital services,'' even when furnished by clinical staff of the hospital. While we used the term ''licensed clinicians'' in the proposed rule to describe the personnel furnishing a post-discharge home visit to CJR model beneficiaries, for purposes of consistency with correct coding guidelines, hereinafter we will instead use the term ''clinical staff'' as it is defined in the CPT coding guidelines. Specifically, in the ''CPT Coding Guidelines, Introduction, Instructions for Use of the CPT Codebook'' it says, a ''clinical staff member is a person who works under the supervision of a physician or other qualified health care professional, and who is allowed by law, regulation and facility policy to perform or assist in the performance of a specific professional service, but does not individually report that professional service.''

We proposed that up to 9 post-discharge home visits could be billed and paid during each 90-day post-anchor hospitalization CJR episode. Given the average PAC length of stay of approximately 45 days for these episodes and the incentives under CJR to improve efficiency, which may shorten PAC stays, 9 visits would represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded PAC in an efficient episode. In the proposed rule, we stated our belief that a home visit of once a week to a non-homebound beneficiary who has concluded PAC and who could also receive services in the physician's office or hospital outpatient department as needed, along with telehealth visits in the home from a physician or NPP as proposed, should be sufficient to allow comprehensive assessment and management of the beneficiary throughout the LEJR episode. We proposed that the service be billed with HCPCS code GXXXX (CJR model, home visit for patient assessment performed by a qualified health care professional for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and making beneficiary connections to community and other services; (for use only in the Medicare approved CJR model); may not be billed for a 30 day period covered by a transitional care management code) and paid at approximately $50 under the MPFS. We proposed that the standard MPFS ratesetting methodologies would establish relative value units (RVUs) based on the resources required to furnish the typical service. We stated that final RVUs under the CY 2016 MPFS for the proposed new HCPCS code for CJR home visits would be included in the CJR final rule. In addition, we proposed to update the values each year to correspond to final values established under the MPFS.

The waiver would not apply with respect to a CJR beneficiary who has qualified, or would qualify, for home health services when the visit was furnished. We discussed our expectation that the visits by clinical staff could include patient assessment, monitoring, assessment of functional status and fall risk, review of medications, assessment of adherence with treatment recommendations, patient education, communication and coordination with other treating clinicians, care management to improve beneficiary connections to community and other services, etc. These post-discharge home visits would remove barriers to follow-up care outside of the

home with providers and suppliers and allow the beneficiary to be treated in his or her home environment or place of residence, where potential safety concerns, such as tripping hazards, could quickly be identified and remediated. Given these occasions for further patient assessment and intervention, we stated out belief that where such post-discharge home visits are furnished, there are opportunities to increase patient-centered care coordination and decrease episode spending, potentially resulting in higher quality care for beneficiaries and increased episode efficiency which may benefit the beneficiaries, the Medicare Trust Fund, and participant hospitals.

We also proposed to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. The MPFS payment for the surgical procedure includes 90 days of post-operative care furnished by the surgeon. Post-operative follow-up care is not separately billable by the surgeon. We note that in the proposed rule we had incorrectly stated that Medicare limits the separate billing of post-operative care when there is a transfer of care to another practitioner. The current construction of the global packages included in MPFS payments reflects a more narrow view of surgical follow-up care that does not encompass broader, more comprehensive models of post-operative care, such as an episode model like CJR. As we have noted in the past, it is also difficult to determine the appropriate valuation of the various components of the current global packages (2015 Physician Fee Schedule 79 FR 67584). We did not believe that the CJR post-discharge home visits, which can include nursing assessments for chronic conditions for which care may be affected by the surgery, would replace or substantially duplicate the kind of post-operative visits involved in furnishing post-operative follow-up care for the global surgery procedure under the MPFS. Instead, we anticipated that the work of these post-discharge visits would be similar to the work furnished by the physician coordinating the patient's overall episode care. Therefore, we proposed to waive the global surgery billing rules to allow the surgeon or other practitioners to furnish and bill for the post-discharge home visits during surgical global periods.

In the proposed rule, we noted that we planned to monitor utilization patterns of post-discharge home visits under CJR to monitor for overutilization and significant reductions in medical home health services. We sought comments on the proposed waiver of the ''incident to'' direct physician supervision requirement to pay for a maximum number of post-discharge home visits to beneficiaries who do not qualify for home health services by clinical staff under the general supervision of a physician.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters commended CMS for the proposal to waive the ''incident to'' direct physician supervision requirement to allow a CJR beneficiary who does not qualify for home health services to receive post-discharge visits in his or her home or place of residence any time during the episode. The commenters believe these home visits will provide participant hospitals with a useful tool for care coordination and management that will ultimately improve the quality and reduce the cost of an LEJR episode extending 90 days following hospital discharge. The commenters asserted that the flexibility afforded by these post-discharge home visits and the latitude for testing different configurations of visits will be very valuable to the development of new care pathways for LEJR patients, to CJR model beneficiaries' health, and to overall participant hospital episode quality and payment performance. In addition, several commenters specifically commended CMS for proposing to waive current Medicare billing rules in order to allow the separate reporting of these post-discharge home visits during surgical global periods. These commenters explained that this proposal would allow the clinical staff of orthopedic surgeons engaged in care management throughout the CJR beneficiary's episode to furnish post-discharge home visits to address beneficiary health concerns, where the resources required for the surgeon to coordinate the beneficiary's overall episode of care during the global surgical period are not accounted for in the typical case used under the MPFS to price the global period for the surgical procedure.

*Response:* We agree that allowing post-discharge home visits to be furnished to non-homebound CJR model beneficiaries may contribute to improved care coordination and management and stronger patient engagement, ultimately resulting in better health outcomes and reduced episode spending. We also believe it is appropriate for these visits to be paid separately in addition to payment for the surgical procedure, if they are furnished during the global surgical period ''incident to'' the services of the physician who performed the surgical procedure.

*Comment:* Several commenters recommended that CMS permit home visits under the ''incident to'' direct physician supervision waiver, regardless of whether or not the beneficiary qualified for home health services. These commenters believe that participant hospitals should have the full flexibility to determine the most efficient and appropriate way to furnish home nursing visits to beneficiaries who would qualify for home health services, including those who are homebound.

*Response:* While we appreciate the commenters' suggestions that we provide maximal flexibility to participant hospitals to deliver the configuration of services the hospital believes to be most appropriate to manage a beneficiary's care, we continue to believe that home visits furnished under the ''incident to'' direct physician supervision waiver should be limited to CJR model beneficiaries who otherwise would not qualify for home health services. We note that while home health episodes are 60 days in duration, payment adjustments are made for beneficiaries who require only a few visits during the episode or who are discharged during the home health episode. Therefore, CJR model beneficiaries who qualify for home health services could receive home health services that would be appropriately paid even if they qualified for such services for less than 60 days. Those beneficiaries who qualify for home health services for any duration of time during the CJR model episode would not need to receive post-discharge home visits under the ''incident to'' direct physician supervisions waiver. Furthermore, we expect that homebound CJR model beneficiaries may typically need other types of services provided under the home health benefit than just post-discharge home visits by clinical staff, including skilled nursing services, therapy services, medical supplies, and medical social services. We would not expect that post-discharge home visits provided under the ''incident to'' direct physician supervision waiver would adequately substitute for home health services under the more comprehensive Medicare home health benefit. For those beneficiaries receiving home health care, paying additionally for post-discharge home visits under the ''incident to'' direct physician supervision waiver would be duplicative of services that should be furnished under the home health episode and could lead to ineffective care coordination and management due

to the involvement of multiple clinical staff working for different organizations or physician practices.

*Comment:* Many commenters expressed support for CMS's proposal to pay for up to 9 post-discharge home visits under the proposed ''incident to'' direct physician supervision waiver for CJR model beneficiaries during episodes of care. These commenters asserted that 9 post-discharge home visits should be sufficient to address the care coordination and management needs of beneficiaries throughout the episode during the time when those beneficiaries are not homebound. Other commenters recommended that CMS should not limit the number to 9 visits because such a limit inappropriately prescribes patterns of care. In the context of bundled payment that provides a target price for the episode, these commenters believe that providers should be able to furnish any number of home visits they believe is appropriate based on the beneficiary's clinical condition and that there is no risk of overutilization due to the pre-established target price. Other commenters arguing in favor of the proposal for up to 9 post-discharge home visits further recommended that CMS revisit the maximum number of visits over the course of the model and increase the maximum number permitted based on the early experience of model participants if a higher number of post-discharge visits seems warranted.

*Response:* While we understand that some commenters would prefer no limit or a higher limit on the number of post-discharge home visits, as discussed previously these visits are restricted to CJR model beneficiaries who do not quality for home health services. The commenters did not offer specific clinical rationale for setting a higher maximum number of post-discharge home visits. Moreover, we continue to believe it is appropriate to limit the number of post-discharge home visits that can be paid under the CJR model to mitigate the risk of overutilization, especially in the early years of the model where participant hospitals have no, or limited, repayment responsibility for excess actual episode spending above the target price. Thus, we continue to believe that it is most appropriate to allow up to 9 post-discharge home visits during a CJR model episode, which should be sufficient for the episode period when CJR model beneficiaries would not qualify for home health services. As we discussed in the proposed rule, 9 visits would represent a home visit on average of once per week for two-thirds of the 90-day episode duration, the period of time when the typical beneficiary may have concluded PAC in an efficient episode. We are not prescribing the periodicity, pattern, or number of these visits for model beneficiaries. We will monitor utilization of these visits and may revisit the maximum number of visits over the course of the model based on the implementation experience of participant hospitals.

*Comment:* Several commenters requested that CMS permit HHAs to bill and be paid for the post-discharge home visits under the proposed ''incident to'' direct physician supervision waiver. They asserted that such a policy would allow HHA expertise and experience to contribute to LEJR episode efficiency and quality because HHAs routinely furnish effective home nursing visits to homebound beneficiaries. A commenter pointed out that beneficiaries receiving home health care have especially low hospital readmission rates compared to beneficiaries receiving PAC from other types of providers. A number of commenters asserted that allowing HHAs to furnish home visits outside of home health episodes of care would contribute to continuity of care for CJR model beneficiaries, as nurses from the HHA with established relationships with the beneficiary and his or her family could continue to furnish home visits when the beneficiary was no longer homebound and, therefore, not eligible for home health services.

Some commenters suggested that HHAs furnishing post-discharge home visits could be paid under the MPFS at the same rate as physicians, while other commenters suggested that HHAs should be paid at the HHPPS discipline-specific LUPA rates for the post-discharge home visits. Commenters pointed out that HHAs regularly carry out assessment home visits paid by commercial insurers, and asserted that allowing HHAs to furnish home visits to CJR model beneficiaries who are not in a home health episode would provide opportunities for physician groups to partner with HHAs on needed interventions.

Some commenters recommended that other organizations be allowed to furnish and be paid for home visits to CJR model beneficiaries, including community-based organizations and hospitals. A few commenters asserted that hospitals should be able to send nurses to a CJR beneficiary's home and bill directly for the services, rather than a hospital-based physician billing for those services. Finally, a commenter suggested that nurse practitioners be allowed to bill for the home visits.

*Response:* We appreciate the commenters' suggestions that we permit HHAs and other organizations and providers to furnish post-discharge home visits to CJR model beneficiaries. We note that nurse practitioners may currently furnish and bill for home care visits that are paid by Medicare under the usual MPFS rules. Under our proposal, post-discharge home visits would be furnished ''incident to'' a physician's professional services while under the general supervision of a physician. In some cases, this may be the orthopedic surgeon who performed the surgical procedure during the anchor hospitalization, and in other cases it may be a physician identified by the participant hospital to assume care coordination and management responsibility following the beneficiary's discharge from the initial hospital stay. The regulations at § 410.26 outline specific limitations on ''incident to'' services. We require that services and supplies furnished ''incident to'' a physician's professional service must be—

- Furnished in a noninstitutional setting to a non-institutional patient.
- An integral, though incidental, part of the services of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
- Commonly furnished without charge or included in the bill of a physician (or other practitioner).
- Of a type that are commonly furnished in the office or clinic of a physician (or other practitioner)
- Furnished under direct supervision of the physician or practitioner.
- Furnished by the physician, practitioner with an ''incident to'' benefit, or auxiliary personnel.
- A physician (or other practitioner) may be an employee or independent contractor.

Although we proposed to waive the direct physician supervision requirement in § 410.26(b)(5) as previously discussed, clinical staff providing post-discharge home visits as ''incident to'' services would still need to be considered ''auxiliary personnel'' (employed, contracted, or leased employee of the physician or same employing organization as physician) as required by § 410.26(a)(1) and § 410.26(b)(6). Therefore, it would not be permissible for HHAs, community-based organizations, hospitals, or others to provide post-discharge home visits under the proposed ''incident to'' direct physician supervision waiver as these entities would not meet the definition of ''auxiliary personnel'' as outlined in regulation. At this time, we are declining to waive any additional

requirements of the ''incident to'' rules that would be necessary for these other entities to furnish CJR post-discharge home visits because we continue to believe that the post-discharge home visits should always be ''incident to'' a physician's professional services, including that they are an integral, although incidental, part of the physician's professional services in the course of the diagnosis or treatment of an illness of injury, and that they are furnished by auxiliary personnel (if not by the physician or practitioner with an ''incident to'' benefit), who by definition are linked to the physician (or employing organization of the physician) by employment, contract, or lease. We believe the ''incident to'' relationship of post-discharge home visits to a physician's professional services is critical due to the importance of robust care coordination and close care management to episode cost and quality performance, given the lengthy, broadly defined CJR episodes. We note that in the case where a post-discharge home visit is furnished by clinical staff employed by the hospital, the hospital could bill under the MPFS if the supervising physician who is an employee or a contractor of the hospital has reassigned his or her benefits to the hospital.

As a result, we are not providing additional waivers for post-discharge home visits to beneficiaries in the CJR model who otherwise do not qualify for Medicare home health services, other than under our proposal to allow for 9 post-discharge home visits under the ''incident to'' direct physician supervision waiver. We further note that under BPCI, post-discharge home visits consistent with the goals of episode payment for LEJR procedures are furnished under a similar ''incident to'' direct physician supervision waiver, and BPCI participants have not expressed concerns that the waiver limits their ability to efficiently provide the necessary visits. This leads us to believe that the limited waiver of only the direct physician supervision requirement for ''incident to'' post-discharge home visits that we are providing under the CJR model will be sufficient.

*Comment:* Several commenters recommended that CMS require physician claims for post-discharge home visits to identify and document the specialties of clinical staff providing the visit. They recommended that billing for services provides no information about the process of care coordination, which would be important to understand success under the model test. The commenters expressed concern that the waiver of the ''incident to'' direct physician supervision requirement could allow a non-qualified clinician to provide follow up care to CJR beneficiaries, supervised only by a hospital contractor. Several commenters requested that CMS further specify the clinical staff who can furnish post-discharge home visits to CJR model beneficiaries. Finally, another commenter inquired whether a nurse, physical therapist, or occupational therapist could furnish the visit under the order of a physician.

*Response:* We appreciate the interest of the commenters in understanding the roles of various clinical staff in care coordination under the CJR model. However, we do not plan to collect specific information about the clinical staff who furnish post-discharge home visits under this waiver of the ''incident to'' direct physician supervision requirement because this would be administratively burdensome to the physicians involved who are not themselves participants in the CJR model and, we believe, unnecessary to ensure the delivery of safe, medically necessary services. We proposed to waive only the direct physician supervision requirement for ''incident to'' services in order to permit general physician supervision for these home visits. All other Medicare rules for coverage and payment of services ''incident to'' a physician's service continue to apply, including that the personnel meet the definition of ''auxiliary personnel'' (requiring a relationship with the billing professional); that the services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness; and that the services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner) and must be in compliance with state law. Thus, we do not believe it is necessary to apply a different standard or other requirements to post-discharge home visits permitted under the CJR model. We also will not further define the clinical staff that can furnish the post-discharge home visit but would refer readers to the description of clinical staff in the CPT coding guidelines that we provided earlier in this section. We further note that the HCPCS G-code descriptor for the post-discharge home visits includes various activities that must be in the clinical staff's scope of practice, as would be true for any service furnished ''incident to'' a physician's service. Finally, the evaluation approach to the model as described in section IV. of this final rule will yield information about care redesign approaches and their association with quality and cost performance under the CJR model.

*Comment:* Several commenters expressed support for the proposed level of payment for the post-discharge home visits, agreeing that this should provide adequate payment for the service. A few commenters recommended that $50 would not cover the cost of a home visit by any licensed provider and recommended that CMS substantially increase the payment amount for the visits to reflect the fair market value of the services.

*Response:* In response to commenters recommending a higher payment for the post-discharge home visits, we note that we have experience with home visits being furnished to model beneficiaries under BPCI, and BPCI participants have not expressed concern about the MPFS payment for post-discharge home visits under that model that are priced in the same way as our proposal for payment of such visits under the CJR model. We proposed to use the standard MPFS ratesetting methodologies to establish the MPFS RVUs based on the resources required to furnish the typical CJR model post-discharge home visit service. We did not receive any specific information from commenters about the resources required to furnish these CJR model post-discharge home visits that would lead us to adjust our proposed rule estimate of the resources required to furnish the typical CJR model post-discharge home visit service, which is similar to the BPCI post-discharge home visit service. Therefore, we are not changing our methodology for determining the payment for the CJR model post-discharge home visit under the MPFS. We have crosswalked the RVUs for the CJR model post-discharge home visit directly from those used for the similar service under BPCI, because we estimate that the typical resources to furnish these services under the two models are the same. We provide specific information on the final HCPCS post-discharge home visit G-code and CY 2016 pricing in the following Table 26.

*Comment:* Several commenters recommended that CMS waive the ''incident to'' direct physician supervision requirement for services other than just post-discharge home visits. The commenters recommended that CMS pay for those services using existing CPT codes and their RVUs under the MPFS in order to ensure appropriate payment for the resources

required. Infusion therapy was identified as a service for which the waiver should be provided, in order to allow CJR model beneficiaries who experience post-surgical infections to receive infusion therapy at home, a practice that commenters believe would improve the efficiency of the episode and increase beneficiary satisfaction with care.

*Response:* We appreciate the requests that CMS waive the ''incident to'' direct physician supervision requirement for services other than post-discharge home visits. However, we do not agree with the commenters that such a waiver is necessary for the CJR model because we believe existing Medicare program policies and other proposed waivers of program rules for this model, such as the proposed telehealth waiver, will provide sufficient flexibility to meet the episode care management and care coordination needs for CJR model beneficiaries in a variety of facility, office, and home settings after discharge from the anchor hospitalization.

In the specific clinical scenario cited by the commenters, we note that there are already several circumstances in which CMS may cover and pay for home infusions under existing Medicare program rules should a beneficiary develop a post-surgical infection that is not preventable following LEJR surgery and that requires treatment with intravenous antibiotics. For example, many post-surgical beneficiaries will be homebound for a period of time, and skilled nursing visits for infusion would be covered under the home health benefit if the beneficiary is homebound and has no willing and able caregiver that could administer such a service. In addition, aDME for an infusion pump would be covered under the DME benefit if the drug being infused is included on the national coverage determination (NCD) for infusion pumps (*https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&DocID=280.14&SearchType=Advanced&bc=IAAAABAAAAAA&*). If an infusion pump is covered under DME, Prosthetics, Orthotics, and Supplies (DMEPOS), the DME supplier is required to set up the equipment and provide the training necessary to teach the patient how to infuse themselves at home. Infusion therapy may also be furnished in SNFs, physicians' offices, and hospital outpatient departments. Thus, because coverage is readily available to beneficiaries, we do not believe it is necessary to waive the ''incident to'' direct physician supervision requirement for other services, including infusion therapy, in order to allow them to be furnished in the beneficiary's home under the general supervision of a physician.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal, without modification, to waive the ''incident to'' direct physician supervision requirement set forth at § 410.26(b)(5), to allow a CJR beneficiary who does not qualify for home health services to receive up to 9 post-discharge visits in his or her home or place of residence any time during the episode following discharge from an anchor hospitalization. We will allow clinical staff, such as nurses, considered ''auxiliary personnel'' as defined in § 410.26(a)(1), to furnish the service under the general, rather than direct, supervision of a physician. In some situations the clinical staff providing these services may be employees of the participant hospital and, as long as these clinical staff are supervised by a physician and the appropriate relationship exists between the physician and the clinical staff, payment under the MPFS can be made. Services furnished under the waiver will be billed under the MPFS by the physician or NPP or by the entity, including a hospital, to which the supervising physician or NPP has reassigned his or her benefits. We are also waiving current Medicare billing rules in order to allow the separate reporting by the physician who performed the LEJR procedure of these post-discharge home visits during surgical global periods when he or she is providing the general supervision of the post-discharge home visit.

The post-discharge home visit will be billed with the HCPCS code displayed in Table 26. This code will be payable for CJR model beneficiaries beginning April 1, 2016, the start date of the first CJR model performance year as discussed in section III.C.2.a. of this final rule. Rather than finalizing the specific RVUs for this new HCPCS code in this final rule, we are finalizing them through reference to the RVUs for another HCPCS G-code paid under the MPFS, which will be released in proximity to this rule. Specifically, the RVUs for this new code will be based upon the same inputs used to determine the CY 2016 payment rate for HCPCS code G9187 (BPCI initiative home visit for patient assessment performed by a qualified health care professional for individuals not considered homebound including, but not limited to, assessment of safety, falls, clinical status, fluid status, medication reconciliation/management, patient compliance with orders/plan of care, performance of activities of daily living, appropriateness of care setting; (for use only in the Medicare-approved BPCI initiative); may not be billed for a 30-day period covered by a transitional care management code), the specific HCPCS G-code currently used to report post-discharge home visits under BPCI. We are crosswalking the RVUs for new HCPCS code G9490 to the RVUs for the existing post-discharge home visit HCPCS G-code for the BPCI model because, given our view of the similarities between these two services in the two different models and the similar HCPCS G-code descriptors, we expect the resources required to be the same so the two codes are assigned the same inputs under the standard MPFS ratesetting methodologies. In summary, we are finalizing the policy in this CJR final rule that the new HCPCS code G9490 for CJR model post-discharge home visits will have the same RVUs as HCPCS code G9187 for BPCI model post-discharge home visits, and we will finalize the RVUs for HCPCS code G9187 in the CY 2016 MPFS final rule.

The final CY 2016 RVUs, geographic practice cost indices and conversion factor that determine the MPFS payment for HCPCS code G9187 will be included in the CY 2016 MPFS final rule. We will annually update the RVUs for HCPCS code G9490 for post-discharge home visits for CJR model beneficiaries by crosswalking the RVUs for HCPCS code G9490 to HCPCS code G9187as part of the annual MPFS update, and information on the update will be included in the MPFS final rule each year.

TABLE 26—HCPCS CODE FOR POST-DISCHARGE HOME VISITS FOR CJR MODEL BENEFICIARIES

| HCPCS code No. | Long descriptor | Short descriptor | RVUs equal to those of this HCPCS code for same calendar year under the MPFS |
|---|---|---|---|
| G9490 ..... | CJR model, home visit for patient assessment performed by clinical staff for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring beneficiary connections to community and other services. (for use only in the Medicare-approved CJR model); may not be billed for a 30 day period covered by a transitional care management code. | Joint replac mod home visit ..... | G9187. |

Beneficiaries will be able to receive post-discharge home visits furnished under the ''incident to'' direct physician supervision waiver only during the CJR LEJR episode. All other Medicare rules for coverage and payment of services ''incident'' to a physician's service continue to apply.

The final post-discharge home visit policies are set forth at § 510.600, which has been revised to use the term clinical staff instead of licensed clinician, as well as to eliminate references to licensed clinician and supervising physician employment relationships that are unnecessary because all other ''incident to'' coverage and payment policies continue to apply. The waiver of certain post-operative billing restrictions under the MPFS global surgery rules is set forth at § 510.615.

We note that we plan to monitor utilization patterns of post-discharge home visits under CJR to monitor for overutilization or significant reductions in home health services. c. Billing and Payment for Telehealth Services

As discussed in the previous section, in the proposed rule, we described our expectation that the CJR model design features would lead to greater interest on the part of hospitals and other providers and suppliers caring for CJR beneficiaries in furnishing services to beneficiaries in their home or place of residence, including physicians' professional services. While physicians and NPPs may furnish and be paid by Medicare for home visits under the MPFS, few visits are actually furnished to Medicare beneficiaries because of the significant physician and NPP resources required for such visits and the general structure of most physician and non-physician practitioner office-based practices. For example, in 2014 only 2.6 million physician or NPP home E/M visits were furnished to Medicare beneficiaries in contrast to almost 250 million office or other outpatient evaluation and management visits furnished by physicians or NPPs. CJR would create new incentives for comprehensive episode care management for beneficiaries, including early identification and intervention regarding changes in health status following discharge from the anchor hospitalization. We discussed our understanding that participant hospitals may want to engage health care professionals in furnishing timely visits to homebound or non-homebound CJR beneficiaries in their homes or places of residence to address concerning symptoms or observations raised by beneficiaries themselves, by clinicians furnishing home health services, or by clinical staff furnishing post-discharge home visits, but physicians and NPPs committed to LEJR care redesign may not be able to revise their practice patterns to meet this home visit need for CJR beneficiaries.

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the eight types of originating sites specified in section 1834(m)(4)(C)(ii) of the Act, and the site must satisfy at least one of the requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. These sites include the following:

- Offices of physicians or practitioners.
- Hospitals.
- CAHs.
- RHCs
- Federally Qualified Health Centers.
- Hospital-based or CAH-based Renal Dialysis Centers (including satellites).
- SNFs.
- CMHCs.

Generally, for Medicare payment to be made for telehealth services under the MPFS, several conditions must be met, as set forth under § 410.78(b). Specifically, the service must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. For the list of approved Medicare telehealth services, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html.* Under section 1834(m)(4)(F)(ii) of the Act, we have an annual process to consider additions to and deletions from the list of telehealth services. We do not include any services as telehealth services when Medicare does not otherwise make a separate payment for them.

Some literature suggests that technologies that enable health care providers to deliver care to patients in locations remote from providers are being increasingly used to complement face-to-face patient-provider encounters in both urban and rural areas.[49] In these

[49] Telehealth in an Evolving Health Care Environment: Workshop Summary (2012).

cases, the use of remote access technologies may improve the accessibility and timeliness of needed care, increase communication between providers and patients, enhance care coordination, and improve the efficiency of care. We noted that certain professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services, and thus do not require a waiver to be considered as telehealth services. Such services that do not require the patient to be present in person with the practitioner when they are furnished are covered and paid in the same way as services delivered without the use of telecommunications technology when the practitioner is in person at the medical facility furnishing care to the patient.

In other CMS episode payment models, such as BPCI Models 2 and 3, we determined it was necessary to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act. This waiver allows telehealth services to be furnished to eligible telehealth individuals when they are located at one of the eight originating sites at the time the service is furnished via a telecommunications system but without regard to the site meeting one of the geographic site requirements. For CJR, we proposed a waiver of this same provision as well as waiver of the requirement that the eligible telehealth individual be in an originating site when the otherwise eligible individual is receiving telehealth services in his or her home or place of residence. This waiver would allow providers and suppliers furnishing services to CJR beneficiaries to utilize telemedicine for beneficiaries that are not classified as rural and to allow the greatest degree of efficiency and communication between providers and suppliers and beneficiaries by allowing beneficiaries to receive telehealth services at their home or place of residence. In the proposed rule, we stated our belief that these waivers are essential to maximize the opportunity to improve the quality of care and efficiency for LEJR episodes under CJR.

Specifically, like the telehealth waiver for BPCI, we proposed to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Waiver of this requirement would allow beneficiaries located in any region to receive services related to the episode furnished via telehealth, as long as all other Medicare requirements for telehealth services are met. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that was not excluded from the CJR episode definition (see section III.B.2. of this final rule) could be furnished to a CJR beneficiary, regardless of the beneficiary's geographic location. Under CJR, this waiver would support care coordination and increasing timely access to high quality care for all CJR beneficiaries, regardless of geography. Additionally, we proposed to waive, only for the purpose of testing the CJR model, the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Specifically, we proposed to waive the requirement only when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that was not excluded from the CJR episode definition (see section III.B.2. of the final rule) could be furnished to a CJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. For example, subsequent hospital care services could not be furnished to beneficiaries in their home since those beneficiaries would not be inpatients of the hospital.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters expressed support for CMS's proposal to waive the geographic site requirements for telehealth services to allow beneficiaries in any community to receive telehealth services. The commenters believe that this proposal would allow CJR participant hospitals the flexibility and opportunity to deliver needed professional services via telehealth throughout LEJR episodes in order to improve care coordination and management and respond timely to beneficiary health changes over the course of the episode. They urged CMS to finalize this proposal.

*Response:* Many commenters supported our proposal to waive the geographic site requirements for telehealth services. We agree with the commenters that this waiver may benefit CJR beneficiaries by allowing them to receive clinically appropriate telehealth services regardless of their geographic region, especially given the national breadth of the final selected MSAs for the model.

*Comment:* Many commenters expressed support for CMS's proposal to waive the originating site requirements of the Act that specify the facility or office site at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. The commenters believe that home telehealth services would allow timely access to needed care for CJR model beneficiaries, improve communication among health care professionals caring for the beneficiary, enhance care coordination, and contribute to improved beneficiary adherence to recommended treatments. Several commenters suggested that home telehealth services could be especially valuable for specialist physicians treating beneficiaries for surgical complications, such as infectious disease specialists providing consultation on post-surgical infections. Commenters urged CMS to finalize this proposal.

Additionally, several commenters recommended that CMS modify the proposed waiver to waive the originating site requirements of the Act to allow telehealth services to be delivered to a model beneficiary when the beneficiary is not in a facility, office, or home. A commenter provided the example of a beneficiary experiencing an acute event while in a car who could pull the car off the road and access needed medical services via telehealth for treatment of his or her condition if CMS applied the proposed waiver to sites other than the home.

*Response:* Commenters supported our proposal to allow telehealth services to be covered when furnished in the CJR beneficiary's home or place of residence. We agree that home telehealth services may play an important role in ensuring efficient, high quality episode care for beneficiaries recovering at home following a major lower extremity surgical procedure furnished during an anchor hospitalization.

We do not agree with commenters who suggested we apply this waiver

Available at: *http://www.ic4n.org/wpcontent/uploads/2014/06/IoM%20Telehealth%202012%20Workshop%20Summary.pdf.* Accessed on June 7, 2015.

beyond the beneficiary's home or place of residence. Given the breadth of originating sites under section 1834(m)(4)(C)(ii) of the Act, which include the office of a physician or practitioner, a CAH, a rural health clinic, a federally qualified health center, a hospital, a hospital-based or CAH-based renal dialysis center (including satellites), a SNF, and a community mental health center (CMHC), and our waiver to allow telehealth services in the model beneficiary's home or place of residence, we do not believe it is necessary to include additional locations for beneficiaries to receive telehealth services during a CJR model episode. For urgent needs while traveling or otherwise not at home, we expect beneficiaries would seek care as they currently would for such circumstances to ensure timely services. For non-urgent needs, consistent with coordinated episode care that is a goal of the CJR model, we expect that beneficiaries would seek care from treating physicians and NPPs that could be delivered in one of the sites permitted under the statute and our limited waiver of the originating site requirements.

*Comment:* Several commenters recommended that CMS provide additional waivers that would allow payment for telehealth services other than those on the list of Medicare-approved telehealth services. Some commenters suggested that CMS should allow payment of any services delivered by telehealth, while other commenters requested that CMS permit certain additional services to be furnished by telehealth. Requested services include telemental health, teleconsultations, telenursing, and home monitoring services, including those services that are currently bundled and not separately paid by Medicare. Given that CJR beneficiaries are in LEJR episodes and would commonly require substantial rehabilitation services during their post-operative recovery period, many commenters recommended that CMS allow telerehabilitation services to be furnished by telehealth, including physical therapy, occupational therapy, and speech language pathology services.

*Response:* We appreciate the interest of the commenters in furnishing additional services to CJR model beneficiaries via telehealth. However, do not agree that we should waive additional requirements to increase the list of services that surpass those currently on the Medicare-approved telehealth list. We note that some of the requested services, including individual psychotherapy and certain other mental health services, are already on the Medicare-approved list of telehealth services and could, therefore, be furnished to a CJR beneficiary during an episode in the beneficiary's home or place of residence or at any geographic location under our proposed waiver. Certain consultation services, such as initial inpatient or emergency department consultations or follow-up inpatient hospital or SNF consultations, are also already on the Medicare-approved telehealth list and could be furnished via telehealth regardless of a CJR beneficiary's geographic location under our proposed waiver. We do not believe it would be appropriate to pay separately for currently bundled services, as this could lead to duplicate payment. Furthermore, we do not believe it would be appropriate to add rehabilitation services to the telehealth list as we expect that in-person therapy services already will be available to many CJR model beneficiaries in the home, such as during home health care episodes or furnished by therapists in private practice. We note that the CJR episode payment model is testing episode payment to improve care coordination and management to achieve higher quality care at a lower cost and, therefore, it is not a telehealth model testing the quality and cost outcomes due to different services furnished by telehealth. Thus, we plan to continue to rely on the list of Medicare-approved telehealth services to specify those services that may be furnished via telehealth to CJR beneficiaries. That list is updated annually and is posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html*.

*Comment:* Several commenters recommended that CMS waive the existing requirements that define the interactive telecommunications system that is required for telehealth services to mean multimedia communication equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Some commenters specifically recommended that CMS permit store and forward technologies to be used, while other commenters suggested that CMS let providers determine the manner in which the specific telehealth service could be furnished, such as store and forward, passive remote monitoring, or audio only, assuming all other requirements for billing the services are met. These commenters recommended that such changes would expand access to telehealth services for CJR model beneficiaries who would benefit from enhanced monitoring and care management.

*Response:* We appreciate the information from commenters on alternative approaches to providing care to patients that are not in-person. We note that the CJR model is not testing a telehealth model and, therefore, we do not intend to fundamentally change the scope of telehealth requirements for payment under Medicare. Rather, we proposed to waive certain existing telehealth requirements to provide participant hospitals with additional tools to improve episode quality and efficiency given the constraints on physician time for in-person visits at distant locations or in the beneficiary's home. The proposed waivers would allow greater physician engagement via telehealth in CJR beneficiary care coordination and management following surgery, regardless of the beneficiary's geographic location or home location. We believe that under the CJR model it is important for beneficiaries to receive telehealth services in a way that permits them to interact with treating health care professionals in real-time, including being able to both see and interact with those providers, and the treating health care professionals being able to see and listen to the beneficiaries. Beneficiaries recovering at home following major joint replacement surgery benefit from meaningful engagement in care that is patient-centered in order to improve their understanding and adherence to treatment regimens. Therefore, we do not believe it would be appropriate to allow telehealth services to be furnished to CJR model beneficiaries that do not meet the existing Medicare telehealth requirements for communications technology.

*Final Decision:* After consideration of the public comments received, we are finalizing our proposal, without modification, to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Any service on the list of Medicare-approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary, regardless of the beneficiary's geographic location. We

also are finalizing our proposal to waive the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system only when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. Any service on the list of Medicare approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence. We will continue to require that telehealth services furnished under the CJR model telehealth waiver be furnished using an interactive telecommunications system, consistent with the current requirement for payment of telehealth services under the MPFS.

The existing set of codes used to report evaluation and management (E/M) visits are extensively categorized and defined by the setting of the service, and the codes describe the services furnished when both the patient and the practitioner are located in that setting. Section 1834(m) of the Act provides for particular conditions under which Medicare can make payments for office visits when a patient is located in a health care setting (the originating sites authorized by statute) and the eligible practitioner is located elsewhere. However, in the proposed rule, we stated that we did not believe that the kinds of E/M services furnished to patients outside of health care settings via real-time, interactive communication technology are accurately described by any existing E/M codes. This would include circumstances when the patient is located in his or her home and the location of the practitioner is at another location. Therefore, in order to create a mechanism to report E/M services accurately under the CJR model, we proposed to create a specific set of HCPCS G-codes to describe the E/M services furnished to CJR beneficiaries in their homes via telehealth when the physician or practitioner is in another location.

Among the existing E/M visit services, we stated that we envision these services would be most similar to those described by the office and other outpatient E/M codes. Therefore, we proposed to structure the new codes similarly to the office/outpatient E/M codes but adjusted to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, we proposed to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services, (CPT codes 99201 through 99205 for new patient visits and CPT codes 99212 through 99215 for established patient visits). For example, in the proposed rule we discussed a HCPCS G-code for a level 3 E/M visit for an established patient would be a telehealth visit for the evaluation and management of an established patient in the patient's home, which requires at least 2 of the following 3 key components:

- An expanded problem focused history.
- An expanded problem focused examination.
- Medical decision making of low complexity.

Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the patient's or family's needs or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real-time, audio and video intercommunications technology. The preceding text would be included in the code descriptor for the proposed level 3 established patient telehealth E/M visit HCPCS G-code, just as this information is currently included in the code descriptor for the corresponding level 3 established patient office/outpatient E/M CPT code.

In the proposed rule, we noted that we were not proposing a HCPCS G-code to parallel the level 1 office/outpatient visit for an established patient, since that service does not require the presence of the physician or other practitioner. We stated our belief that this would duplicate the home visits for non-homebound beneficiaries previously discussed in this section.

We proposed to develop payment rates for these new telehealth G-codes for E/M services in the patient's home that are similar to the payment rates for the office/outpatient E/M services, since the codes will describe the work involved in furnishing similar services. Therefore, we proposed to include the resource costs typically incurred when services are furnished via telehealth. In terms of the relative resource costs involved in furnishing these services, in the proposed rule we stated our belief that the efficiencies of virtual presentation generally limit resource costs other than those related to the professional time, intensity, and MP risk to marginal levels. Therefore, we proposed to adopt work and MP RVUs associated with the corresponding level of office/outpatient codes as the typical service because the practitioner's time and intensity and MP liabilities when conducting a visit via telehealth are comparable to the office visit. We stated that final RVUs under the CY 2016 MPFS would be included in the CJR final rule. Additionally, we proposed to update these values each year to correspond to final values established under the MPFS.

We considered whether each level of visit typically would warrant support by auxiliary licensed clinical staff within the context of the CJR model. The cost of such staff and any associated supplies, for example, would be incorporated in the practice expense (PE) RVUs under the MPFS. For the lower level visits, levels 1 through 3 for new visits and 2 and 3 for established visits, we did not believe that the visit would necessarily require auxiliary clinical staff to be available in the patient's home. We anticipated these lower level visits would be the most commonly furnished and would serve as a mechanism for the patient to consult quickly with a practitioner for concerns that can be easily described and explained by the patient. We did not propose to include PE RVUs for these services, since we did not believe that virtual visits envisioned for this model typically incur the kinds of costs included in the PE RVUs under the MPFS. For higher level visits, we typically would anticipate some amount of support from auxiliary clinical staff. For example, wound examination and minor wound debridement would be considered included in an E/M visit and would require licensed clinical staff to be present in the beneficiary's home during the telehealth visit in order for the complete service to be furnished. We stated our belief that it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CJR beneficiaries in LEJR episodes without licensed clinical staff support in the home.

However, we also noted that the proposed model already includes several avenues for licensed clinical staff to be in the patient's home, either through a separately paid home visit as proposed for the model or through home health services as discussed earlier in this final rule. Therefore, although we considered support by auxiliary clinical staff to be typical for level 4 or 5 E/M visits furnished to CJR beneficiaries in

the home via telehealth, we did not propose to incorporate these costs through PE RVUs. Given the anticipated complexity of these visits, we noted that we would expect to observe level 4 and 5 E/M visits to be reported on the same claim with the same date of service as a home visit or during a period of authorized home health care. If neither of these occurs, we proposed to require the physician to document in the medical record that auxiliary licensed clinical staff were available on site in the patient's home during the visit and if they were not, to document the reason that such a high-level visit would not require such personnel.

We noted that because the services described by the HCPCS G-codes for the proposed model, by definition, are furnished remotely using telecommunications technology, they therefore are paid under the same conditions as in-person physicians' services and they do not require a waiver to the requirements of section 1834(m) of the Act. We also noted that because these home telehealth services would be E/M services, all other coverage and payment rules regarding E/M services would continue to apply.

We additionally noted that under the CJR model, this proposal to waive the originating site requirements and create new home visit telehealth HCPCS codes would support the greatest efficiency and timely communication between providers and beneficiaries by allowing beneficiaries to receive telehealth services at their places of residence.

The following is a summary of the comments received and our response.

*Comment:* Several commenters expressed support for CMS's proposal to establish specific HCPCS G-codes for reporting telehealth visits furnished in the beneficiary's home or place of residence. They believe these codes would facilitate tracking these services and improve understanding of the role of these visits in episode care. Several commenters suggested that the resources required to deliver these visits would be similar to the existing CPT office and other outpatient care E/M visit codes paid under the MPFS, consistent with CMS's proposal. A commenter suggested that as the CPT Editorial Panel develops CPT codes to report telehealth services, CMS should consider their use in the future for the CJR model.

*Response:* We agree that currently specific HCPCS G-codes are the most appropriate way for telehealth visits furnished in the CJR beneficiary's home or place of residence to be reported and paid. We have established that the work and MP RVUs for these new HCPCS G-codes will be the same as those for the comparable office and other outpatient E/M visit codes under the CY 2016 MPFS. The HCPCS G-codes, their descriptors, and the CPT codes upon which their RVUs are based are displayed in Table 27. As noted in the proposed rule, we will not be including PE RVUs in the payment rate for these unique CJR model services as we believe any practice expenses incurred to furnish these services are marginal or are paid for through other MPFS services. Accordingly, we are waiving section 1834(m)(4)(2)(B) to allow this deviation from the payment of office/outpatient visits for purposes of the CJR model telehealth in-home visit services. Finally, we will consider new CPT codes as they are released according to our usual processes, and will specifically evaluate whether they may be used in the future to report home telehealth visits for CJR model beneficiaries.

*Final Decision:* After considering the public comments we received, we are finalizing our proposal, without modification, to create 9 HCPCS G-codes to report home telehealth E/M visits furnished under the CJR waiver as displayed in Table 27. These codes will be payable for CJR model beneficiaries beginning April 1, 2016, the start date of the first CJR model performance year as discussed in section III.C.2.a. of this final rule. Rather than finalizing the RVUs for the new HCPCS codes in this final rule, we are finalizing them through reference to the RVUs for other CPT codes paid under the MPFS as equal to the work and MP RVUs that will be established for the comparable office/outpatient visits in the CY 2016 MPFS final rule.

The final CY 2016 RVUs, geographic practice cost indices and conversion factor that determine the payment rates for the CPT codes will be included in the CY 2016 MPFS final rule.

We will update the RVUs for the CJR model HCPCS telehealth G-codes annually by crosswalking them to the corresponding CPT codes as part of the annual MPFS update, and information on the updates will be included in the MPFS final rule each year.

TABLE 27—HCPCS CODES FOR TELEHEALTH VISITS FOR CJR MODEL BENEFICIARIES IN HOME OR PLACE OF RESIDENCE

| HCPCS Code No. | Long descriptor | Short descriptor | Work and MP RVUs Equal to Those of the Corresponding Office/ Outpatient E/M Visit CPT Code for Same Calendar Year under the MPFS |
|---|---|---|---|
| G9481 ..... | Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components:<br>• A problem focused history;<br>• A problem focused examination; and<br>• Straightforward medical decision making, furnished in real time using interactive audio and video technology.<br>Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. | Remote E/M new pt 10mins. | 99201 |

TABLE 27—HCPCS CODES FOR TELEHEALTH VISITS FOR CJR MODEL BENEFICIARIES IN HOME OR PLACE OF RESIDENCE—Continued

| HCPCS Code No. | Long descriptor | Short descriptor | Work and MP RVUs Equal to Those of the Corresponding Office/ Outpatient E/M Visit CPT Code for Same Calendar Year under the MPFS |
|---|---|---|---|
| G9482 | Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components:<br>• An expanded problem focused history;<br>• An expanded problem focused examination;<br>• Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology | Remote E/M new pt 20mins. | 99202 |
| G9483 | Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components:<br>• A detailed history;<br>• A detailed examination;<br>• Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. | Remote E/M new pt 30mins. | 99203 |
| G9484 | Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components:<br>• A comprehensive history;<br>• A comprehensive examination;<br>• Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. | Remote E/M new pt 45mins. | 99204 |
| G9485 | Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved CJR model, which requires these 3 key components:<br>• A comprehensive history;<br>• A comprehensive examination;<br>• Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. | Remote E/M new pt 60mins. | 99205 |
| G9486 | Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components:<br>• A problem focused history;<br>• A problem focused examination;<br>• Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. | Remote E/M est. pt 10mins. | 99212 |

TABLE 27—HCPCS CODES FOR TELEHEALTH VISITS FOR CJR MODEL BENEFICIARIES IN HOME OR PLACE OF RESIDENCE—Continued

| HCPCS Code No. | Long descriptor | Short descriptor | Work and MP RVUs Equal to Those of the Corresponding Office/ Outpatient E/M Visit CPT Code for Same Calendar Year under the MPFS |
|---|---|---|---|
| G9487 ..... | Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components:<br>• An expanded problem focused history;<br>• An expanded problem focused examination;<br>• Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. | Remote E/M est. pt 15mins. | 99213 |
| G9488 ..... | Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components:<br>• A detailed history;<br>• A detailed examination;<br>• Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology | Remote E/M est. pt 25mins. | 99214 |
| G9489 ..... | Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved CJR model, which requires at least 2 of the following 3 key components:<br>• A comprehensive history;<br>• A comprehensive examination;<br>• Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. | Remote E/M est. pt 40mins. | 99215 |

With respect to home health services paid under the HH PPS, in the proposed rule we emphasized that telehealth visits under this model cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. Furthermore, telehealth services by social workers could not be furnished for CJR beneficiaries who are in a home health episode of care because medical social services are included as home health services per section 1861(m) of the Act and paid for under the Medicare HH PPS. However, telehealth services permitted under section 1834 of the Act and furnished by physicians or other practitioners, specifically physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, nurse anesthetists, psychologists, and dieticians, could be furnished for CJR beneficiaries who are in a home health episode of care. Finally, sections 1835(a) and 1814(a) of the Act require that the patient has a face-to-face encounter with the certifying physician or an allowed NPP working in collaboration with or under the supervision of the certifying physician before the certifying physician certifies that the patient is eligible for home health services. Under § 424.22(a)(1)(v), the face-to-face encounter can be performed up to 90 days prior to the start of home health care or within 30 days after the start of home health care. Section 424.22(a)(1)(v)(A) also allows a physician, with privileges, who cared for the patient in an acute or PAC setting (from which the patient was directly admitted to home health) or an allowed NPP working in collaboration with or under the supervision of the acute or PAC physician to conduct the face-to-face encounter.

Although sections 1835(a) and 1814(a) of the Act allow the face-to-face encounter to be performed via telehealth, we did not propose that the waiver of the telehealth geographic site requirement for telehealth services and the originating site requirement for telehealth services furnished in the CJR beneficiary's home or place of residence would apply to the face-to-face encounter required as part of the home health certification when that encounter is furnished via telehealth. In other words, when a face-to-face encounter furnished via telehealth was used to meet the requirement for home health certification, the usual Medicare

telehealth rules would apply with respect to geography and eligibility of the originating site. We discussed our expectation that this policy would not limit CJR beneficiaries' access to medically necessary home health services because beneficiaries receiving home health services during a CJR episode would have had a face-to-face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a PAC facility stay prior to discharge directly to home health services.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters recommended that CMS waive additional telehealth requirements to allow HHAs, physical therapists, occupational therapists, and speech language pathologists to furnish telehealth services to CJR model beneficiaries.

*Response:* Commenters expressed interest in increasing the types of providers and suppliers eligible to deliver telehealth services to CJR model beneficiaries; however, we believe it is most appropriate to continue to limit the health care professionals who can furnish telehealth services under the CJR model to those currently authorized to provide telehealth services under the statute, specifically, physicians, nurse practitioners, physician assistants, nurse-midwives, clinical nurse specialists, certified registered nurse anesthetists, clinical psychologists, clinical social workers, and registered dieticians or nutrition professionals. Given the services on the Medicare-approved telehealth list and CMS's experience with telehealth services furnished by currently eligible physicians and practitioners, we do not believe it is necessary to increase the types of practitioners eligible to provide telehealth services under the CJR model. As discussed earlier in this section, we are not adding additional types of services to the telehealth list and, therefore, we do not see a need to add other types of health care professionals to the list of those currently authorized to furnish telehealth services. We note that the model is not a test of telehealth services and that the proposed telehealth waivers under the CJR model are designed to increase the opportunities for care management and coordination for this test of episode payment. Finally, we expect that CJR model beneficiaries in home health episodes of care will commonly receive in-home health nursing visits and therapy services by HHAs on a regular basis. We note that while we expect the proposed telehealth waivers to increase access to services in the home where otherwise beneficiaries would not have access to such services, this would not hold true for HHAs who typically currently provide services in the home to Medicare beneficiaries under existing program rules.

*Comment:* Several commenters recommended that CMS permit the certification for home health services to occur via telehealth, regardless of the geographic location of the beneficiary, as well as at the beneficiary's home or place of residence.

*Response:* Commenters expressed interest in broadening the circumstances in which home health certification may occur via telehealth, as discussed previously we do not believe that the limitations under current law will lead to access problems for CJR model beneficiaries. During a CJR episode most beneficiaries would have had a face-to-face encounter with either the physician or an allowed NPP during their anchor hospitalization or a physician or allowed NPP during a PAC facility stay prior to discharge directly to home health services. Therefore, the usual Medicare telehealth rules would apply to these CJR beneficiaries with respect to geography and eligibility of the originating site.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, without modification, to allow telehealth services furnished under the CJR model waiver of telehealth requirements to be furnished only by physicians and practitioners currently eligible to furnish Medicare-approved telehealth services under the MPFS. In addition, the usual Medicare rules regarding geography and originating site will continue to apply to the face-to-face encounter required for home health certification.

As we further discussed in the proposed rule, under the proposed waiver of the geographic site requirement and originating site requirement, all telehealth services would be required to be furnished in accordance with all Medicare coverage and payment criteria, and no additional payment would be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service would be waived if there is no facility as an originating site (that is, the service was originated in the beneficiary's home). Finally, providers and suppliers furnishing a telehealth service to a CJR beneficiary in his or her home or place of residence during the episode would not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service. Beneficiaries would be able to receive services furnished in accordance with the telehealth waivers only during the CJR LEJR episode.

The following is a summary of the comments received and our response.

*Comment:* Several commenters recommended that CMS pay a technology fee for telehealth services originating in a model beneficiary's home, comparable to the facility originating site fee. The commenters recommended that such a fee was necessary to pay the costs of technology required in the home for a beneficiary to receive a telehealth visit furnished via a real-time interactive telecommunications system.

*Response:* We appreciate the commenters' perspective on the beneficiary's technology needs for telehealth visits. However, we do not plan to provide a fee because we believe that in most circumstances, the technology can be available to the beneficiary in the home if necessary for a telehealth visit without requiring additional resources. Many beneficiaries may already have such technology in their home, such as a computer with the needed capacity. In addition, we expect that clinical staff furnishing visits paid under a home health episode of care or providing post-discharge home visits will commonly carry such technology that could be used if the timing of the telehealth visit is coordinated with the presence of such clinical staff in a beneficiary's home. We expect that in some cases, efficient and effective care management during an episode may result in closer collaboration among treating providers and clinical staff caring for CJR beneficiaries such that such coordinated visits may occur. As discussed earlier in this section, we believe that it would be rare for a practitioner to conduct as complex and detailed a service as a level 4 or 5 E/M home visit via telehealth for CJR beneficiaries in LEJR episodes without licensed clinical staff support in the home. Finally, we note that as discussed in section III.C.10.a.(2) of this final rule, participant hospitals are permitted to furnish certain beneficiary incentives to CJR beneficiaries, including items of technology that could be used for a beneficiary telehealth visit.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposal, without

modification, to waive the facility fee for telehealth services furnished in a beneficiary's home or place of residence under the CJR model.

*Summary of Final Decisions:* For CJR model beneficiaries, with the exception of the existing geographic site requirement for a face-to-face encounter for home health certification, we are finalizing our proposal, without modification, to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. Any service on the list of Medicare-approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary, regardless of the beneficiary's geographic location. For CJR model beneficiaries, with the exception of the existing originating site requirement for a face-to-face encounter for home health certification, we are also finalizing our proposal, without modification, to waive the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system only when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode. Any service on the list of Medicare-approved telehealth services and reported on a claim with an ICD–10–CM principal diagnosis code that is not excluded from the CJR episode definition (see section III.B.2. of this final rule) can be furnished to a CJR beneficiary in his or her home or place of residence, unless the service's HCPCS code descriptor precludes delivering the service in the home or place of residence.

We are also finalizing our proposal, without modification, to create 9 HCPCS G-codes to report home telehealth E/M visits furnished under the CJR waiver of telehealth requirements as displayed in Table 27. These codes will be payable for CJR model beneficiaries beginning April 1, 2016. We are also waiving the requirement that the same payment made for comparable office/outpatient visits be made to eligible distant site practitioners for services reported with the new HCPCS G-codes that we are creating for the CJR model to reflect that these CJR model telehealth home visit services do not require significant practice expenses. In addition, we are finalizing our proposal, without modification, that if a level 4 or 5 home telehealth visit is furnished and a post-discharge home visit is not billed on the same claim with the same date of service or the beneficiary is not in a period of authorized home health care, we will require that the physician or NPP furnishing the home telehealth visit document the presence of auxiliary licensed clinical staff in the home or include an explanation in the medical record as to the specific circumstances precluding the need for auxiliary staff for the specific telehealth visit. Finally, providers and suppliers furnishing a telehealth service to a CJR beneficiary in his or her home or place of residence during the episode will not be permitted to bill for telehealth services that were not fully furnished when an inability to provide the intended telehealth service is due to technical issues with telecommunications equipment required for that service.

Under the waiver of the geographic site requirement and originating site requirement for the CJR model, we are finalizing our proposal, without modification, that no additional payment will be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for a telehealth service will be waived if there is no facility as an originating site (that is, the service is originated in the beneficiary's home).

All other requirements for Medicare coverage and payment of telehealth services not otherwise waived in this final rule will continue to apply, including the list of services approved to be furnished by telehealth and the eligible distant site practitioners. Beneficiaries can receive services furnished under the telehealth waivers only during the CJR LEJR episode.

The final telehealth policies are set forth at § 510.605. We have revised § 510.605(a) and (b) to clarify that the telehealth waivers do not apply to the requirements for a face-to-face encounter for home health certification. We have revised § 510.605(c) to specify the two waivers of selected payment provisions, moving the waiver of the facility fee if the telehealth service is provided in the beneficiary's home from proposed § 510.605(b)(2) to § 510.605(c)(1) and adding § 510.605(c)(2) for the waiver of the payment requirements under section 1834(m)(2)(B) for the in-home telehealth visit HCPCS G-codes created for the CJR model. We have renumbered proposed § 510.605(c) to new (d).

We note that we plan to monitor patterns of utilization of telehealth services under CJR to monitor for overutilization or reductions in medically necessary care, and significant reductions in face-to-face visits with physicians and NPPs. We will specifically monitor the distribution of new telehealth home visits, as we anticipate greater use of lower level telehealth visits than higher level telehealth visits for CJR model beneficiaries. Given our concern that auxiliary clinical staff be present for level 4 and 5 visits furnished remotely, we will also monitor whether these visits are billed on the same claim with the same date of service as a post-discharge home visit or during a period of authorized home health care, and, if neither of the prior two conditions are met, whether our final requirement that the physician or NPP document the presence of auxiliary licensed clinical staff in the home or include an explanation in the medical record as to the specific circumstances precluding the need for auxiliary staff for the specific visit is met.

d. SNF 3-Day Rule

In the proposed rule, we discussed our expectation that the CJR model would encourage participant hospitals and their provider and supplier partners to redesign care for LEJR episodes across the continuum of care extending to 90 days post-discharge from the anchor hospitalization. We stated our belief that hospitals would seek to develop and refine the most efficient care pathways so beneficiaries receive the lowest intensity, clinically appropriate care at each point in time throughout the episode. We understand that in some cases, particularly younger beneficiaries undergoing total knee replacement, certain beneficiaries receiving LEJR procedures may be appropriately discharged from the acute care hospital to a SNF in less than the 3 days required under the Medicare program for coverage of the SNF stay. While total knee arthroplasty (TKA) remains payable by Medicare to the hospital only when furnished to hospital inpatients, we have heard from some stakeholders that these procedures may be safely furnished to hospital outpatients with a hospital outpatient department stay of only 24 hours. Finally, we noted that the current geometric mean hospital length of stay for LEJR procedures for beneficiaries without major complications or comorbidities (MS–DRG 470) is only 3 days and that for MS–DRG 469 for beneficiaries with such complications or comorbidities is 6 days. Thus, in the

proposed rule we stated our belief that it is possible that hospitals working to increase episode efficiency may identify some CJR beneficiaries who could be appropriately discharged from the hospital to a SNF in less than 3 days, but that early discharge would eliminate Medicare coverage for the SNF stay unless a waiver of Medicare requirements were provided under CJR.

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing or skilled rehabilitation care or both. In accordance with section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than 3-consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. We refer to this as the SNF 3-day rule. We note that the SNF 3-day rule has been waived or is not a requirement for Medicare SNF coverage under other CMS models or programs, including BPCI Model 2. BPCI Model 2 awardees that request and are approved for the waiver can discharge Model 2 beneficiaries in less than 3 days from an anchor hospital stay to a SNF, where services are covered under Medicare Part A as long as all other coverage requirements for such services are satisfied.

Currently, FFS Medicare beneficiary discharge patterns to a SNF immediately following hospitalization for an LEJR procedure vary regionally across the country, from a low of approximately 10 percent of Medicare beneficiaries to a high of approximately 85 percent.[50] Additionally, a study of Medicare beneficiaries has shown that over the period of time between 1991 and 2008, as the inpatient hospital length-of-stay for total hip arthroplasty (THA) decreased from an average of 9.1 days to an average of 3.7 days, the average percentage of primary THA patients discharged directly to home declined from 68 percent to 48 percent while the proportion discharged directly to skilled care (primarily SNFs) increased from 17.8 percent to 34.3 percent,[51] reflecting that nationally there has been increasing SNF utilization over almost two decades for beneficiaries following discharge from a hospitalization for primary THA. Similar to the proposed CJR payment policies that we discuss in section III.C. of this final rule, which would require participating CJR hospitals to repay Medicare for excess episode spending beginning in performance year 2, participants in BPCI Model 2 assume financial responsibility for episode spending for beneficiaries included in a Model 2 episode. Episode payment models like BPCI and CJR have the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The removal of these incentives in an episode payment model lays the groundwork for offering participant hospitals greater flexibility around the parameters that determine SNF stay coverage. BPCI participants considering the early discharge of a beneficiary in accordance with the waiver during a Model 2 episode must evaluate whether early discharge to a SNF is clinically appropriate and SNF services are medically necessary. Next, they must balance that determination and the potential benefits to the hospital in the form of internal cost savings due to greater financial efficiency with the understanding that a subsequent hospital readmission, attributable to premature discharge or low quality SNF care, could substantially increase episode spending while also resulting in poorer quality of care for the beneficiary. Furthermore, early hospital discharge for a beneficiary who would otherwise not require a SNF stay (that is, the beneficiary has no identified skilled nursing or rehabilitation need that cannot be provided on an outpatient basis) following a hospital stay of typical length does not improve episode efficiency under an episode payment model such as BPCI or CJR.

Because of the potential benefits we see for participating CJR hospitals, their provider partners, and beneficiaries, we proposed to waive in certain instances the SNF 3-day rule for coverage of a SNF stay following the anchor hospitalization under CJR beginning in performance year 2 of the model, when we proposed that repayment responsibility for actual episode spending that exceeds the target price would begin. We proposed to use our authority under section 1115A of the Act with respect to certain SNFs that furnish Medicare Part A post-hospital extended care services to beneficiaries included in an episode in the CJR model. We stated our belief that this waiver is necessary to the model test so that participant hospitals can redesign care throughout the episode continuum of care extending to 90 days post-discharge from the anchor hospitalization in order to maximize quality and hospital financial efficiency, as well as reduce episode spending under Medicare. However, we did not propose to waive this requirement in performance year 1, when we did not propose that participating hospitals would be responsible for excess actual episode spending. In the proposed rule, we stated our belief that there is some potential for early hospital discharge followed by a SNF stay to increase actual episode spending over historical patterns unless participant hospitals are particularly mindful of this potential unintended consequence. Without participant hospital repayment responsibility in performance year 1, we were concerned that Medicare would be at full risk under the model for increased episode spending because, without a financial incentive to closely manage care, hospitals might be more likely to discharge beneficiaries to SNFs early, leading to increased episode spending for which the hospital would bear no responsibility. Beginning in performance year 2 and continuing through performance year 5, we proposed to waive the SNF 3-day rule because we proposed that participant hospitals would bear responsibility (capped at the proposed stop-loss limit described in section III.C.8. of this final rule) for excess episode actual spending, thereby providing a strong incentive in those years for participant hospitals to redesign care with both quality and efficiency outcomes as priorities. All other Medicare rules for coverage and payment of Part A-covered SNF services would continue to apply to CJR beneficiaries in all performance years of the model.

In addition, because the average length of stay for Medicare beneficiaries hospitalized for LEJR procedures without major complications or comorbidities is already relatively short at 3 days, and in view of our concerns over protecting immediate CJR beneficiary safety and optimizing health outcomes, we proposed to require that participant hospitals may only discharge a CJR beneficiary under this proposed waiver of the SNF 3-day rule to a SNF with an overall rating of three stars or better by CMS based on information publicly available at the time of hospital discharge. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and the potential for later negative findings alone may not afford sufficient beneficiary protections. CMS

[50] ''Analysis of Medicare claims with admission dates from July 1, 2013 through June 30, 2014 accessed through the Chronic Conditions Warehouse.''

[51] Cram P, Lu X, Kaboli PJ, et al. Clinical Characteristics and Outcomes of Medicare Patients Undergoing Total Hip Arthroplasty, 1991–2008. JAMA. 2011;305(15):1560–1567.

created a Five-Star Quality Rating System for SNFs to allow SNFs to be compared more easily and to help identify areas of concerning SNF performance. The Nursing Home Compare Web site (*www.medicare.gov/NursingHomeCompare/*) gives each SNF an overall rating of between 1 and 5 stars. SNFs with 5 stars are considered to have much above average quality, and SNFs with one star are considered to have quality much below average, while SNFs with three stars are considered to have average quality. Published SNF ratings include distinct ratings of health inspection, staffing, and quality measures, with ratings for each of the three sources combined to calculate an overall rating. These areas of assessment are all relevant to the quality of SNF care following discharge from the anchor hospitalization initiating a CJR episode, especially if that discharge occurs after less than three days in the hospital. A study of the clinical factors that kept patients in a Danish hospital unit dedicated to discharge in three days or fewer following total hip and knee arthroscopy procedures found that that pain, dizziness, and general weakness were the main clinical reasons for longer hospitalization, as well as problems with personal care and walking 70 meters with crutches.[52] Medicare beneficiaries discharged from the hospital to a SNF in less than three days may be at higher risk of these uncomfortable symptoms and disabling functional problems not being fully resolved at hospital discharge, although we expected that under the CJR episode payment model participant hospitals would have a strong interest in ensuring appropriate discharge timing so that hospital readmissions and complications would be minimized. Therefore, because of the potential greater risks following early inpatient hospital discharge, in the proposed rule we stated our belief that it would be appropriate for all CJR beneficiaries discharged from the participant hospital to a SNF in less than 3 days be admitted to a SNF that has demonstrated that it is capable of providing quality care to patients with significant unresolved post-surgical symptoms and problems. We believed such a SNF would need to provide care of at least average overall quality, which would be restated by an overall rating of three-stars or better.

We proposed that the waiver be available for the CJR beneficiary's care. The SNF would insert a Treatment Authorization Code on the claim for a beneficiary in the model where the SNF seeks to the use the waiver. This process would promote coordination between the SNF and the participant hospital, as the SNF would need to be in close communication with the participant hospital to ensure that the beneficiary is in the model at the time the waiver is used. We proposed that where the beneficiary would be eligible for inclusion in a CJR episode of care at the time of hospital discharge, use of the waiver would be permitted where it is medically necessary and appropriate to discharge the beneficiary to a SNF prior to a 3-day inpatient stay.

Beneficiaries would be eligible to receive services furnished under the 3-day rule waiver only during the CJR episode. In the proposed rule, we described our plan to monitor patterns of SNF utilization under CJR, particularly with respect to hospital discharge in less than 3 days to a SNF, to ensure that beneficiaries are not being discharged prematurely to SNFs and that they are able to exercise their freedom of choice without patient steering. We sought comment on our proposal to waive the SNF 3-day stay rule for stays in SNFs rated overall as three stars or better following discharge from the anchor hospitalization in CJR episodes.

The following is a summary of the comments received and our responses.

*Comment:* Most commenters expressed strong support for CMS's proposal to waive the SNF 3-day rule to allow CJR model beneficiaries to be discharged to a SNF after less than a 3-day inpatient hospital stay where such a discharge is clinically appropriate and medical necessary. These commenters stated that this flexibility would be very important to participant hospitals developing partnerships with PAC providers to redesign care for LEJR episodes for CJR model beneficiaries. The commenters agreed with CMS that participant hospitals would be incentivized to use this waiver judiciously because they will be actively managing care with their eye on the approach of downside risk. A commenter estimated that approximately 20 percent of elective joint replacement patients would need to be discharged to a SNF and would be able to do so safely after fewer than 3 inpatient hospital days. A small number of commenters opposed the waiver altogether because of concerns that, without sufficient protections to ensure beneficiaries' readiness for early hospital discharge, bundled payment could encourage premature hospital discharge so hospitals could reduce their internal costs for the anchor hospitalization.

Given the importance of this waiver to care redesign for LEJR episodes, many commenters recommended that CMS implement the waiver in the first performance year of the model, even though CMS proposed that hospitals would have no repayment responsibility in that year. The commenters asserted that participant hospitals would be focused in the first year of the model on creating and implementing episode care processes and procedures in order to achieve successful quality and episode spending performance. These activities would include establishing or reviewing discharge planning protocols and clinical pathways. The commenters stated that if the waiver were unavailable until performance year 2, hospitals would have to undertake many of these activities again in the second performance year, creating inefficiency and unnecessary administrative burden.

*Response:* Commenters supported our proposal of the SNF 3-day rule waiver to allow CJR model beneficiaries to be discharged to a SNF with an overall rating of three stars or better after less than a 3-day inpatient hospital stay. As we discussed in the proposed rule, an episode payment model like CJR has the potential to mitigate the existing incentives under the Medicare program to overuse SNF benefits for beneficiaries, as well as to furnish many fragmented services that do not reflect significant coordinated attention to and management of complications following hospital discharge. The reduction of these incentives in an episode payment model lays the groundwork for offering participant hospitals greater flexibility around the parameters that determine SNF stay coverage. We understand from many current BPCI Model 2 participants engaged in LEJR episodes that this waiver plays an important role in their care redesign efforts to streamline and improve the quality of care, as they work closely with their SNF partners. While we appreciate the concerns of those commenters identifying the need for sufficient protections for beneficiaries, we believe that our proposal to limit use of the SNF 3-day stay rule waiver to discharges of beneficiaries to SNFs with an overall rating of three stars or better, as discussed later in this section, provides sufficient protection against premature hospital discharge, especially in the context of the financial and quality incentives under the model itself.

Regarding the commenters' request to make the SNF 3-day stay rule waiver available to participant hospitals in the

[52] Husted H, Lunn TH, Troelsen A, Gaarm-Larsen L, Kristensen BB, Kehlet H. Why still in hospital after fast-track hip and knee arthroplasty? Acta Orthopaedica. 2011; 82(6)679–684.

first year of the model, we remain concerned that without participant hospital repayment responsibility in performance year 1, hospitals may be more likely to discharge beneficiaries to SNFs early leading to increased episode spending for which the hospital would bear no responsibility. Given that we are delaying the start date of the model to April 1, 2016 as discussed in section III.C.2. of this final rule, we believe hospitals will be engaged in care redesign through most of the 9 months of the shortened performance year 1 and, knowing the waiver will be available in performance year 2, can plan care processes with the appropriate use of the waiver in mind so no duplication of hospital effort will be necessary. Most commenters requesting a delayed start date for the model provided extensive information about the necessary and lengthy preparatory activities required for success under the CJR model, such as obtaining and analyzing CMS data to identify areas for performance improvement, establishing systems to track patients across the continuum of care, and forming the necessary financial arrangements. Many commenters estimated that this work would take 6 to 12 months or more. These commenters suggested that under our proposed start date of January 1, 2016, the participant hospitals moving into performance year 2 would likely have been able to complete only limited work toward restructuring care. Thus, based on our final timeline for the model performance years, the lack of hospital repayment responsibility in performance year 1, and our understanding of the work that will need to be done by participant hospitals to redesign care over the first performance year, we do not believe it is necessary or appropriate to make the SNF 3-day stay rule waiver available in performance year 1 in order to test the CJR model.

*Comment:* Many commenters requested that CMS make the SNF 3-day stay rule available for all medically appropriate CJR beneficiary discharges in less than 3 days from the anchor hospitalization, regardless of the star rating of the admitting SNF. The commenters asserted that such a limitation on the SNFs where a beneficiary could be discharged would limit beneficiary freedom of choice, despite CMS's assertions elsewhere in the rule that beneficiaries would retain freedom of choice about all providers and suppliers. Several commenters questioned what would happen if a beneficiary chose a SNF rated two stars or lower and was discharged in less than 3 days.

The commenters opposing the proposal to allow the waiver to be used only for CJR model beneficiaries' discharges to SNFs with an overall rating of three stars or better recommended that this proposal would create two tiers of separate and unequal care because the percentage of SNFs that meet this requirement in the selected MSAs was so variable. The commenters asserted that participant hospitals located in those MSAs with an adequate supply of three star or greater SNFs, such as where half or more of the SNFs meet the quality requirement, would be able to establish flexible, patient-centered care pathways, where participant hospitals located in those MSAs with an inadequate supply of three star or better SNFs, such as where less than half of the SNFs meet the quality requirement, would need to create more restrictive care pathways driven by CMS's SNF overall star rating requirements. Some commenters estimated that the variation in the percentage of qualifying SNFs in the selected MSAs was 20 percent to 80 percent, and recommended that this variation created an unlevel playing field for hospitals required to participate in the CJR model.

A number of commenters acknowledged the quality rationale for CMS's proposal but stated arguments about why the SNF overall star rating was not appropriate for use as the quality requirement for waiver use. These commenters asserted that the overall star rating provides little information about the quality of care for short stay residents, the category that CJR model beneficiaries would fall into, because few of the assessment questions would apply to them. Some commenters pointed out that the current star rating does not incorporate important measures of quality of care for LEJR episode beneficiaries, such as function, the ability to ambulate, hospital readmissions, and emergency department utilization. Other commenters believe that periodic recalibration activities by CMS that alter SNF scores could lead high quality SNFs working in close partnership with CJR participant hospitals to suddenly become ineligible to treat model beneficiaries under the waiver. These commenters described significant month-to-month fluctuations in SNF overall star ratings for individual SNFs that could be highly disruptive to stable care redesign under the CJR model. Several commenters suggested that SNFs with embedded specialty expertise, such as behavioral health, might be unable to admit CJR model beneficiaries who required that specialized SNF expertise.

Some commenters recommended that CMS provide accommodation for those MSAs with low percentages of qualifying SNFs, but did not specify the parameters that should accompany such accommodation. Other commenters recommended that CMS deem all hospital-owned SNFs eligible for the waiver, regardless of their star rating, or beneficiaries may need to leave their home geographic area. A commenter pointed out that swing beds in CAHs that may function as PAC providers do not have star ratings and, under CMS's proposal, would therefore be ineligible for payment under the SNF 3-day rule waiver for CJR model beneficiaries. The commenter suggested that CMS waive the proposed three star or better requirement when the PAC provider is a CAH swing bed, because these PAC providers can be an excellent choice for rural beneficiaries following an LEJR procedure due to the available resources in the CAH and the proximity of the facility to beneficiary's home.

A number of commenters recommended that CMS modify its proposal to base SNF eligibility on the overall star rating to instead base SNF eligibility on a rating of three stars or better on two of the three criteria used in the overall rating, specifically quality measures and staffing. These commenters recommended that these two criteria are meaningful for LEJR episode patients, while including the state survey criterion (the third criterion in the overall star rating) would lead to large facilities being disadvantaged because state surveyors would be more likely to find deficiencies based on larger numbers of residents. The commenters asserted that different states and different surveyors could lead to unpredictable results on the health inspections criterion for various SNFs that would unfairly affect the overall star rating and, therefore, the ability of SNFs to accept CJR model beneficiaries under the waiver. However, several other commenters pointed out that two of the three criteria used in the SNF overall star rating are self-reported by SNFs without verification, observing that only the annual inspection is derived from assessment by an independent observer.

Several commenters observed that the BPCI SNF quality requirement for use of the waiver is less stringent. BPCI Model 2 Awardees are approved to use the waiver for all of the Awardee's BPCI Model 2 beneficiaries based on their submission of partner SNFs each quarter, where the majority of those

SNFs had a three star or better overall rating for 7 of the 12 months based on the most recent SNF star data. Once approved, however, there is no requirement that a BPCI beneficiary discharged under the waiver actually go to one of the SNFs on the partner list, thereby ensuring beneficiary freedom of choice. The commenters recommended that CMS adopt a similar policy for the CJR model if CMS believes quality criteria must be applied.

*Response:* Commenters expressed concern about our proposal to limit the use of the waiver for CJR model beneficiaries to SNFs with an overall star rating of three stars or better. We reiterate that this proposal applies only to circumstances where the beneficiary is medically appropriate for discharge and requires a SNF stay after less than a 3-day inpatient hospital stay. Medicare will continue to cover SNF stays for CJR model beneficiaries who require SNF care and remain in the hospital 3 days or longer under all existing rules for Medicare coverage and payment of Part A-covered SNF services, and these rules do not include a star rating requirement. In this way, the CJR model waiver of the SNF 3-day stay rule is an extension of existing coverage for a Part A-covered SNF stay, and is not a limit on it.

As we stated in the proposed rule, we continue to believe that because of the potential risk of premature hospital discharge before a beneficiary is medically stable and of care stinting that may result from the financial incentives under the CJR model to reduce actual episode spending and generate hospital internal cost savings, we need to ensure that when a CJR beneficiary is discharged to a SNF before having stayed in the hospital for a qualifying 3-day or longer stay, discharges are to SNFs that provide care of at least average overall quality. Balancing beneficiary protection with the potential for participant hospitals to create patient-centered care pathways that improve quality and episode efficiency, we believe it is most appropriate for all CJR beneficiaries discharged from the participant hospital to a SNF in less than 3 days be admitted to a SNF that has demonstrated that it is capable of providing quality care to patients with significant unresolved post-surgical symptoms and problems. Thus, we believe that establishing a quality performance requirement for SNFs accepting each CJR beneficiary under the waiver is important, especially given the geographic distribution and variety of hospitals included in the CJR model, as well as the estimate from a commenter of the significant number of model beneficiaries (20 percent of elective THA and TKA model beneficiaries) that could be eligible for early hospital discharge to a SNF.

We do not believe that adopting the BPCI Model 2 SNF 3-day stay waiver policy in totality is appropriate. Under BPCI Model 2, so long as the participant identifies sufficient partnerships with SNFs with an overall rating of three stars or better, then the 3-day stay requirement is waived for that participant's discharges of BPCI model beneficiaries, even if beneficiaries are admitted to SNFs with an overall star rating of fewer than three stars. In other words, the 3-day stay rule waiver applies at the level of the financially responsible entity. Moreover, BPCI is a voluntary model where participants sign participation agreements with CMS after having assessed the opportunities under the model and chosen to participate, and can select among 48 different clinical episodes. These design features of BPCI reduce the potential risks of decreased access to care and care stinting. In contrast, under the CJR model which requires participation of substantially all IPPS hospitals in the selected MSAs, where the participant hospitals have varying levels of readiness to develop the care pathways and partnerships necessary for high quality and cost performance under an episode payment model, we believe it is necessary and appropriate to apply the waiver at the SNF level. That is, we believe that in the CJR model, it is necessary to ensure that every CJR beneficiary discharged to a covered SNF stay after less than a 3-day anchor hospitalization is discharged to a SNF that provides care of at least average quality.

In terms of establishing the quality requirement for SNFs accepting CJR model beneficiaries under the waiver, while we appreciate the variation in qualifying SNFs under our proposal across the participating MSAs, we need to balance the goal of improved efficiency under an episode payment model through additional access to a covered SNF stay after an anchor hospitalization of less than 3 days with protecting beneficiaries from the risks of care stinting and premature discharge from the hospital that may result from the financial incentives of episode payment. We estimate that although the national average percentage of SNFs rated three stars or better is greater than 60 percent, the percentage of qualifying SNFs in the MSAs selected for this model range from 22 percent to over 80 percent. However, we note that every MSA does have at least one SNF that would qualify for the waiver under our proposal and, therefore, all CJR model beneficiaries would have access to at least one SNF in the MSA of the participant hospital that meets the SNF overall star rating requirement for the waiver.

We believe it is appropriate to restrict access to the waiver for beneficiaries who are eligible for discharge to a medically necessary SNF stay after less than a 3-day anchor hospitalization to discharge to a SNF with an overall star rating of three stars or better in order to ensure SNF quality and, therefore, protect the beneficiary from potential harm that could arise from the financial incentives of the CJR episode payment model. We believe we need to balance the importance of beneficiary access to the waiver with our concerns about sufficient beneficiary protections under this innovative episode payment model that otherwise alters the rules under which Medicare pays hospitals and allows different financial arrangements among providers and suppliers. Problem areas due to early hospital discharge may not be discovered through model monitoring and evaluation activities until well after the episode has concluded, and we do not believe the potential for later negative findings alone provides sufficient beneficiary protections. Thus, we believe it is appropriate to establish a quality requirement for SNFs accepting patients for Part A-covered stays under the waiver, and believe that participant hospitals will need to convey all relevant information to CJR model beneficiaries who require SNF stays and are candidates for discharge from the anchor hospitalization in less than 3 days. If a CJR beneficiary is discharged to a SNF with an overall rating of two stars or less without a preceding 3-day anchor inpatient hospital stay, the SNF stay will not be covered under Medicare Part A, consistent with existing Medicare rules. However, we note that imposing conditions upon a waiver that, in effect, provides for additional coverage of certain SNF stays is not the same as restricting access to certain SNFs. We are not restricting beneficiary choice of SNFs. We believe it is important for beneficiaries to have unrestricted choice of providers under this model as well as access to SNFs with appropriate specialty expertise or located in their immediate community. We refer readers to section III.F.2. of this final rule for further discussion of the beneficiary choice and notification issues under this model, including their applicability to model beneficiaries who may be discharged in less than 3 days to a SNF.

Finally, for the reasons previously discussed regarding our need to balance access to the waiver with beneficiary protections, we are not making any exceptions to the overall star rating requirement for PAC providers without a star rating or hospital-owned SNFs. We note that all existing Medicare program rules will continue to apply to these providers regarding Part A-covered SNF stays, and CJR model beneficiaries will continue to be able to be discharged to these PAC providers for a Medicare-covered stay as long as the preceding inpatient hospital stay extends at least 3 days.

We appreciate the suggestions of commenters regarding alternatives to using the SNF overall star rating to determine the eligibility of a SNF to be paid for CJR model beneficiaries under the waiver based on the quality of SNF care. However, we continue to believe that SNF overall star ratings reflect important differences in quality among SNFs that are applicable to care for CJR model beneficiaries recovering after LEJR surgery. CMS rates nursing homes on three categories: Results from onsite inspections by trained surveyors, performance on certain quality measures, and levels of staffing. We use these three categories to create an overall star rating, which balances facility-reported information with independent observation. While consumers can see and focus on any of the three individual categories, we believe for purposes of this model that the overall star rating that incorporates all three categories of SNF quality performance in an overall rating is the most appropriate choice to determine SNF eligibility for use of the waiver under the CJR model, based on the SNF's record of average or better care as reflected in the most comprehensive SNF quality rating that takes into account all categories of information about SNF quality.

We acknowledge the disruption to partnerships among hospital participants and SNFs that may occur due to the potential for month-to-month changes in a SNF's quality rating and periodic CMS recalibration. We understand the substantial effort necessary for provider collaboration in care redesign and do not want the SNF 3-day stay waiver policies of the CJR model to unnecessarily disrupt or hamper these partnerships. We proposed to require that participant hospitals may only discharge a CJR beneficiary under the proposed waiver of the SNF 3-day rule to a qualified SNF with an overall rating of three stars or better by CMS based on information publicly available at the time of hospital discharge. However, in order to create more stability in our determination of SNF eligibility based on a pattern of quality performance, and in response to comments, we are modifying our proposal. Under our final policy, we will determine a SNF's qualification for payment under the CJR model waiver based on an overall star rating of three stars or better for at least 7 of the 12 preceding months according to the most recent star rating data available for the quarter in which the CJR beneficiary's admission to the SNF occurs. Specifically, we will prepare and make publicly available a list of qualified SNFs for each calendar quarter of the CJR model performance years, based on our examination of the most recent rolling 12-month period of SNF overall star ratings, and the waiver will apply for admissions to SNFs on our list during the relevant calendar quarter, assuming all other requirements for the waiver are met as discussed in this final rule. The use of such a list to determine qualified SNFs who are eligible for payment under the waiver will facilitate the ease of administration of the policy through CMS's shared systems, as well as ensure a common understanding among participant hospitals, SNFs, CJR model beneficiaries and other providers and suppliers about the specific SNFs who are qualified for Medicare Part A payment under the waiver at any given time in the model performance period.

While we will be using the pattern of SNF quality performance reflected over a rolling 12-month period to qualify SNFs for the 3-day stay waiver under the CJR model, similar to our examination of 12 months of SNF overall star ratings for BPCI partner SNFs, in contrast to BPCI Model 2, the CJR model waiver will only permit a Part A-covered SNF stay if the CJR beneficiary receives care at a qualified SNF, defined as a SNF that meets our quality requirements as determined by its inclusion on the applicable quarterly list of qualified SNFs at the time of the CJR beneficiary's admission to that SNF. In this regard, our standard under the CJR model is more stringent than under BPCI Model 2, in order to provide additional beneficiary protections under this model that includes substantially all IPPS hospitals in 67 MSAs, rather than Awardees participating in a voluntary model such as BPCI. As discussed earlier in this section, we believe that stronger beneficiary protections under the CJR model are necessary due to the required, rather than voluntary, hospital participation in the model, which will include hospitals at varying stages of readiness for engagement in the care redesign and partnerships necessary for high quality and cost performance under episode payment.

We expect that the most recent SNF quality data will lag the admission to the SNF under the CJR by several months, at a minimum. As under BPCI Model 2, we will update our determination of SNFs that qualify for the CJR model waiver every quarter, to ensure that we regularly incorporate updated SNF star ratings reflective of the most recent SNF quality performance into our determinations of SNF eligibility to admit CJR model beneficiaries under the waiver. To minimize any confusion about SNF qualification for participant hospitals and SNFs, we will post to the CMS Web site prior to the beginning of each quarter the list of qualified SNFs who may use the waiver for admissions of CJR model beneficiaries with less than a 3-day anchor hospitalization. We believe the use of a rolling 12-month period to assess SNF qualification based on the pattern of overall star ratings appropriately balances our interest in ensuring SNF quality for a beneficiary during a timeframe that is reasonably close to the CJR beneficiary's admission to the SNF, with our interest in encouraging stable, effective arrangements between SNFs that furnish high quality care and participant hospitals in the CJR model.

*Comment:* Several commenters requested clarification about whether the waiver of the SNF 3-day stay rule would only apply to those CJR model beneficiaries discharged in less than 3 days directly from the anchor hospitalization to a SNF or whether a beneficiary who was discharged to home in less than 3 days but later in the episode developed complications could be admitted to a SNF under the waiver.

*Response:* We note that the waiver under this model would make Part A post-hospital extended stay coverage available, in the context of all other current Medicare rules for coverage and payment of Part A-covered SNF services, to CJR model beneficiaries who are discharged in less than 3 days from the anchor hospitalization. Thus, in regard to the scenario stated by the commenters, if a CJR beneficiary is discharged to home after less than a 3-day inpatient hospital stay and requires SNF services within the first 30 days after discharge from the anchor hospitalization, the CJR beneficiary could be admitted to a SNF for a Part A-covered stay, assuming all other requirements for coverage and payment of Part-A covered SNF services are met and the SNF meets the quality

requirements for use of the waiver by its inclusion on the list of qualified SNFs for the calendar quarter in which the SNF admission occurs.

*Comment:* Several commenters posed a variety of operational questions to CMS about how the proposed waiver would be implemented, such as from whom would a SNF get a treatment authorization code and how could the waiver be used because at the time of SNF billing services could already have been rendered.

*Response:* Commenters expressed interest in a better understanding of the operational plans for implementing the SNF 3-day stay rule waiver. We note that since the waiver will not be available until performance year 2, CMS will publicly release various provider education materials, such as MLN Matters articles, prior to performance year 2 to educate providers regarding the use of the treatment authorization code and other billing instructions. For an example of a MLN Matters article intended for SNFs submitting claims to MACs for BPCI Model 2 beneficiaries that conveys information regarding the waiver use in that model, we refer readers to the CMS Web site at: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8792.pdf*. We note that this is an example only, and providers caring for CJR model beneficiaries should await information specific to the CJR model before making changes to their systems.

We expect that SNFs using this waiver to bill for a Part A-covered SNF stay for a CJR beneficiary discharged from a participant hospital after an inpatient stay of less than 3-days will need to work closely with the participant hospital to determine the applicability of the waiver prior to admitting the beneficiary to the SNF because billing will not occur until after the SNF services are rendered. Specifically all of the following requirements will need to be met for the stay to be covered under the waiver:

- The hospitalization does not meet the prerequisite hospital stay of at least 3 consecutive days for Part A coverage of ''extended care'' services in a SNF. If the hospital stay would lead to covered PAC SNF treatment in the absence of the waiver, then the waiver is not necessary for the stay.
- The discharge is from a participant hospital in the CJR model. Participant hospitals can be confirmed by a posted file on the CMS Web site.
- The beneficiary's discharge is from MS–DRG 469 or MS–DRG 470.
- The beneficiary must have been discharged from the CJR model participant hospital for one of the two specified MS–DRGs within 30 days prior to the initiation of SNF services.
- The beneficiary meets the criteria for inclusion in the CJR model at the time of SNF admission: That is, he or she is enrolled in Part A and Part B, eligibility is not on the basis of ESRD, is not enrolled in any managed care plan, is not covered under a United Mine Workers of American health plan, and Medicare is the primary payer.
- The SNF is qualified to admit CJR model beneficiaries under the waiver on the date of SNF admission based on its overall star rating, which can be confirmed for the applicable date of SNF admission by a posted file on the CMS Web site that identifies qualified SNFs based on their overall star rating of three stars or better for at least 7 of the preceding 12 months. The file will be updated quarterly, reflecting a rolling 12-month period of SNF overall star ratings.

We will provide additional information on the use of this waiver to providers through MLN Matters articles and other methods prior to the beginning of performance year 2. Medicare will not cover and pay under Part A for SNF services under the CJR model SNF 3-day stay rule waiver unless all of the previously stated criteria are met. SNFs who report the treatment authorization code under circumstances where one or more of these criterion are not met will not be paid by Medicare under the waiver.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to waive the SNF 3-day rule for episodes being tested in the CJR model in performance years 2 through 5, with modification of the SNF quality requirements. We will waive the SNF 3-day rule for a CJR beneficiary following the anchor hospitalization only if the SNF is qualified at the time of the CJR beneficiary's SNF admission. We define a qualified SNF as one that has an overall rating of three stars or better in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site for at least 7 of the 12 preceding months, as determined by CMS based on the most recent rolling 12 months of SNF star rating data available for the calendar quarter that includes the date of the beneficiary's admission to the SNF. We will post the list of qualified SNFs quarterly to the CMS Web site. If a SNF is on this list, the other requirements for the waiver as listed previously are met, and other existing Medicare coverage requirements are met, the SNF stay for the CJR beneficiary will be covered under Part A under the CJR model SNF 3-day rule waiver.

Beneficiaries will be able to receive a Part A-covered SNF stay furnished in accordance with the SNF 3-day stay rule waiver only during the CJR episode. All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

The final SNF 3-day stay rule policies are set forth at § 510.610, where § 510.610(a) has been revised to clarify that the waiver applies to SNFs on the calendar quarter list of qualified SNFs and subparagraphs (1) and (2) added to reflect CMS's quarterly determination of qualified SNFs based on their overall rating of three stars or better for at least 7 of the 12 months of rolling data and subsequent posting to the CMS Web site of the list of qualified SNFs for the calendar quarter.

e. Waivers of Medicare Program Rules To Allow Reconciliation Payment or Repayment Actions Resulting From the Net Payment Reconciliation Amount (NPRA)

In order to make reconciliation payment to or carry out repayment from a participant hospital that results from the NPRA calculation for each performance year as discussed in section III.C.6.a. of this final rule, in the proposed rule we stated our belief that we would need to waive certain Medicare program rules. Therefore, in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we proposed to waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the proposed payment model for CJR participant hospitals selected in accordance with CMS's proposed selection methodology. In addition, we did not propose that reconciliation payments or repayments change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part A and Part B services that were paid for CJR beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA. We therefore proposed to waive the requirements of sections 1813 and 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from a participant hospital under the CJR model. We sought comment on our proposed waivers related to repayment and repayment actions as a result of the NRPA calculated.

*Final Decision:* We received no public comments on the proposed waivers of the requirements of sections 1813 and 1833(a) of the Act to the extent that they would otherwise apply to reconciliation payments or repayments from a participant hospital under the CJR model. Therefore, we are finalizing our proposal, without modification, to waive requirements of the Act for all Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the final payment model for CJR participant hospitals selected in accordance with CMS's final selection methodology. Reconciliation payments or repayments will not change beneficiary cost-sharing from the regular Medicare program cost-sharing for the related Part A and Part B services that were paid for CJR beneficiaries and aggregated to determine actual episode spending in the calculation of the NPRA.

This waiver is set forth at new § 510.620.

12. Enforcement Mechanisms

CMS must have certain mechanisms to enforce compliance with the requirements of the model, either by the participant hospital, or by an entity or individual included in the CJR model by furnishing a service to a beneficiary during a CJR episode. The following discussion details the enforcement mechanisms we proposed to make available to CMS for the CJR model.

We proposed an enforcement structure that would be consistent with other CMMI models. We believed that Model 2 of the BPCI initiative is an appropriate model for comparison, given that Model 2 and CJR share many of the same policy characteristics, particularly with respect to episode definition. For example, the participation agreement between CMS and a participant (called an Awardee) in BPCI Model 2 provides that CMS may immediately or with advance notice terminate the awardee's participation in the model or require the Awardee to terminate its agreement (''participant agreement'') with a participating provider or supplier that is not in compliance with BPCI requirements. In such circumstances, CMS may direct the Awardee to terminate its participant agreement with a participating provider or supplier because the Awardee has a participation agreement with CMS, whereas the participating provider or supplier does not. CMS may require termination of the Awardee or a participating provider or supplier if—

- CMS determines that it no longer has the funds to support the BPCI model;
- CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act; or
- The BPCI awardee or an individual or entity participating in BPCI under the awardee does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of the BPCI agreement.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the BPCI initiative.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

Under the terms of the BPCI agreement, upon CMS's termination of the agreement for any of the reasons previously listed in this section, CMS may immediately cease the distribution of positive reconciliation payments to the awardee and the awardee must immediately cease the distribution of any gainsharing payments.

Many CMMI models also allow for CMS to impose remedial actions to address noncompliance by either a participant that has a direct relationship (participation agreement) with CMS, or by any individual or entity participating in the CMMI model pursuant to an agreement with the participant hospital. For example, with respect to the BPCI Model 2, where CMS determines that there may be noncompliance, CMS may take any or all of the following actions:

- Notify the BPCI awardee of the specific performance problem.
- Require the awardee to provide additional data to CMS or its designees.
- Require the awardee to stop distributing funds to a particular individual or entity.
- Require the awardee to forgo the receipt of any positive reconciliation payments from CMS.
- Request a corrective action plan from the awardee.

++ If CMS requests a corrective action plan, then the following requirements apply to awardees in the BPCI initiative:

—The awardee must submit a corrective action plan for CMS approval by the deadline established by CMS.

—The corrective action plan must address what actions the awardee will take within a specified time period to ensure that all deficiencies are corrected and that it remains in compliance with the BPCI agreement.

Under the CJR model, we proposed that CMS would have the enforcement mechanisms detailed in this section available for use against participant hospitals and any entity or individual furnishing a service to a beneficiary during a CJR episode, where the participant hospital or such entity or individual: (1) Does not comply with the CJR model requirements; or (2) is identified as noncompliant via CMS' monitoring of the model or engage in behavior related to any of the reasons previously described that apply to the BPCI initiative. These mechanisms will support the goals of CJR to maintain or improve quality of care. Given that participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with other providers or suppliers (''CJR collaborators'') we believed that enhanced scrutiny and monitoring of participant hospitals and CJR collaborators under the model is necessary and appropriate. Participant hospitals and CJR collaborators will also be subject to all existing requirements and conditions for Medicare participation not otherwise waived under section 1115A(d)(1) of the Act.

We proposed that CMS would have the option to use any one or more of the following enforcement mechanisms for participant hospitals in CJR. We further proposed that these enforcement mechanisms could be instituted and applied in any order, as is consistent with other CMMI models:

- Warning letter—We proposed to give CMS the authority to issue a warning letter to participant hospitals to put them on notice of behavior that may warrant additional action by CMS. This letter would inform participant hospitals of the issue or issues identified by CMS leading to the issuance of the warning letter.
- Corrective Action Plan—We proposed to give CMS the authority to request a corrective action plan from participant hospitals. We proposed the following requirements for corrective action plans:

++ The participant hospital would be required to submit a corrective action plan for CMS approval by the deadline established by CMS.

++ The corrective action plan would be required to address what actions the

participant hospital will take within a specified time period to correct the issues identified by CMS.

++ The corrective action plan could include provisions requiring that the participant hospital terminate collaborator agreements with CJR collaborators that are determined by HHS to be engaging in activities involving noncompliance with the provisions of this final rule, engaged in fraud or abuse, providing substandard care, or experiencing other integrity problems.

++ The participant hospital's failure to comply with the corrective action plan within the specified time period could result in additional enforcement action, including: (1) Termination; (2) automatic forfeiture of all or a portion of any reconciliation payments as that term is defined in section III.C. of the proposed rule; (3) CMS's discretionary reduction or elimination of all or a portion of the hospital's reconciliation payment; or (4) a combination of such actions.

• Reduction or elimination of reconciliation amount—We proposed to give CMS the authority to reduce or eliminate a participant hospital's reconciliation amount based on noncompliance with the model's requirements, negative results found through CMS' monitoring activities, or the participant hospital's noncompliance associated with a corrective action plan. For example, where CMS requires a participant hospital to submit a corrective action plan, the result of the participant hospital's failure to timely comply with that requirement could be a 50 percent reduction in the reconciliation amount due to the participant hospital at the end a performance year, where the participant hospital's reconciliation report reflects a positive reconciliation amount. We solicit comments on whether negative monitoring results and noncompliance with program requirements or corrective action plans should result in automatic forfeiture of all or a portion of positive NPRA, the amount that could be forfeited or reduced, the number of performance periods over which NPRA may be forfeited or reduced per instance or episode of noncompliance, whether the amount should be a fixed percentage of NPRA or a variable amount depending on the nature and severity of the noncompliance, and the criteria CMS should use in deciding the severity of noncompliance.

Where the participant hospital's reconciliation report reflects a repayment amount, forfeiture of a reconciliation amount would not be an option for that performance year. In such a case, we considered whether CMS would require the participant hospital to forfeit a certain percentage of a reconciliation amount in the reconciliation report for a future performance year. However, in the case of a failure to comply with the model's requirements, presence of negative results found through CMS's monitoring activities, or noncompliance associated with a corrective action plan, we believed a policy that would increase the amount of repayment amount on the reconciliation report for the performance year in which the noncompliance occurred by the participant hospital is more likely to result in compliance from the hospital. Therefore, we proposed to add 25 percent to a repayment amount on a reconciliation report, where the participant hospital fails to timely comply with a corrective action plan or is noncompliant with the model's requirements. We sought comments on this forfeiture policy, including the percentage to be added to a repayment amount on a reconciliation report; the number of performance periods over which a reconciliation amount may be forfeited or reduced per instance or episode of noncompliance; whether the amount should be a fixed percentage of a reconciliation amount or repayment amount, as applicable, or a variable amount depending on the nature and severity of the noncompliance; and the criteria CMS should use in deciding the severity of noncompliance.

• Termination from the model—Given the provisions we proposed outlining the participation of hospitals in the model, we believed that, in contrast to other CMS models, termination from the CJR model would contradict the model's design. As a result, in some circumstances termination from the model may be unlikely to be a sufficient mechanism to deter noncompliance by participant hospitals. While we believed termination is a remedy unlikely to be frequently used by CMS in this model, we nonetheless leave open the possibility that in extremely serious circumstances termination might be appropriate, and for that reason, we proposed to include it as an available enforcement option. Where a participant hospital is terminated from the CJR model, we proposed that the hospital would remain liable for all negative NPRA generated from episodes of care that occurred prior to termination. We proposed that CMS may terminate the participation in CJR of a participant hospital when the participant hospital, or a CJR collaborator that has a collaborator agreement with a participant hospital and performs functions or services related to CJR activities, fails to comply with any of the requirements of the CJR model. We further proposed that CMS could terminate the participant hospital's participation in the model, or require a participant hospital to terminate a collaborator agreement with a CJR collaborator for reasons including, but not limited to the following:

• CMS determines that it no longer has the funds to support the CJR model.

• CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act.

• The CJR participant hospital, or an individual or entity participating in CJR under the participant hospital does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of this final rule.

++ Takes or fails to take any action that CMS determines for program integrity reasons is not in the best interests of the CJR model.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

++ Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model.

• Other Enforcement Mechanisms—We seek to incorporate policies regarding enforcement mechanisms that are necessary and appropriate to test the CJR model. Thus, we sought public comment on additional enforcement mechanisms that would contribute to the following goals:

++ Allow CMS to better operate or monitor the model.

++ Appropriately engage and encourage all entities and individuals furnishing a service to a beneficiary during a CJR episode to comply with the requirements and provisions of the CJR model.

++ Preserve the rights of Medicare beneficiaries to receive medically necessary care, to not be endangered by providers and suppliers engaging in noncompliant activities, and to be able to choose from whom they want to receive care.

We sought public comment on these proposals and invited commenters to propose additional safeguards we should consider in the final rule.

The following is a summary of the comments received and our responses.

*Comment:* Several comments focused on our proposal regarding termination of participant hospitals from the model. Most of these comments recommended that we add requirements such as the provision of substandard care and patient steering to the list of circumstances meriting termination. Another related line of comments suggested that a participant hospital should be appropriately penalized if it is found to have provided substandard care, delayed or withheld medically necessary care, or engaged in patient steering.

*Response:* Issues associated with care stinting, provision of substandard care, or denial of medically necessary care are serious matters. In no way does this final rule permit providers and suppliers furnishing services to beneficiaries in a CJR episode to engage in these sorts of behaviors. Thus, we appreciate the comments on this matter and the opportunity to clarify how we have included protections for beneficiaries by including language at § 510.410(b) that allows CMS to take action against any participant hospital that takes any action that threatens the health or safety of patients. Providers and suppliers furnishing services to CJR beneficiaries must comply with applicable Medicare CoPs and similar requirements. Nothing in this final rule alters the CoPs and similar requirements for providers and suppliers that furnish services to CJR beneficiaries. If a participant hospital or its CJR collaborator is found to have taken any action that threatens the health or safety of patients, including but not limited to withholding or delaying medically necessary care, providing substandard health care, or steering beneficiaries to certain providers or suppliers, this final rule allows CMS to take action against the participant hospital that is noncompliant or has a collaborator agreement with the noncompliant entity. These actions include the institution of corrective action plans, reduction or elimination of reconciliation payments, increased repayment amounts, and termination from the model. Furthermore, existing laws, rules, and regulations governing these matters also continue to apply to providers and suppliers furnishing services to CJR beneficiaries. Where HHS (including CMS and OIG) discovers noncompliance with existing laws, rules, and regulations, participation in the CJR model would not provide protection for participant hospitals or CJR collaborators engaging in actions that implicate care stinting, provision of substandard care, denial of medically necessary care, or any other scheme or action that is illegal or causes beneficiary harm.

*Comment:* Other commenters stated that CMS should strengthen the accountability of participant hospitals by implementing a separate financial penalty for hospitals found to have deliberately withheld medically necessary care or steered a patient toward a health care provider known to be delivering substandard care. Commenters suggested that such a penalty should be sizable enough to act as a disincentive for hospitals and other providers that might consider stinting as potentially profitable.

*Response:* As we described in our previous response, given the enforcement mechanisms delineated in this final rule, as well as the prevalence of existing laws, rules, and regulations prohibiting care stinting, provision or substandard care, or denial of medically necessary care, we believe that it unnecessary to implement processes for a separate financial penalty specifically for this model outside of the enforcement mechanisms we have already proposed. Where a participant hospital engages in these behaviors, CMS could consider reducing or eliminating that participant hospital's reconciliation payment, as well as notifying our Federal program integrity colleagues and, where appropriate, law enforcement, of such behavior, particularly in instances in which HHS (including CMS and OIG) discovered knowing violations or patterns of violations of requirements that directly impacted the safety and health of patients.

*Comment:* Some commenters suggested that CMS specify the amount by which it would reduce a reconciliation payment in instances of noncompliance. By contrast, other commenters recommended that CMS should have the discretion to assess penalties based on the severity of the violation or noncompliance; the degree of negligence, recklessness, or willful behavior of the parties; and evidence of patterns or practice of noncompliance or violations by participant hospitals. These commenters suggested that CMS should not be locked into a set penalty percentage, but rather should take into account all the facts and circumstances of each confirmed noncompliance or violation and set a penalty that is appropriate to address the problem and encourage improvement by the parties.

*Response:* We appreciate comments on this issue and agree with the latter group of commenters. We intend to exercise our authority to reduce or eliminate a participant hospital's reconciliation payment based on the severity of the noncompliance. We believe that this is a prudent approach, particularly given that, as some commenters noted, these instances are often complex and fact-specific. However, we are finalizing our proposal to add 25 percent to a repayment amount on the participant hospital's reconciliation report in the following circumstances: (1) CMS has required a corrective action plan from a participant hospital; (2) the participant hospital is not due a positive reconciliation payment but instead owes a repayment amount to CMS; and (3) the participant hospital fails to timely comply with a corrective action plan or is noncompliant with the model's requirements. This provision is added as new § 510.410(b)(3).

We leave open the possibility for future rulemaking on the issue of enforcement mechanisms for this model. We believe that providing, at a minimum, a non-exhaustive list of the types of behaviors against which CMS would use each of these enforcement mechanisms could offer useful clarification for participant hospitals and CJR collaborators.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal with a modification to apply these enforcement mechanisms only to participant hospitals. We also have included a non-exhaustive list of examples of behaviors that may lead to application of these enforcement mechanisms. These policies are set forth in regulation at § 510.410.

We had proposed that CMS would have the enforcement mechanisms detailed in this section available for use against participant hospitals and any entity or individual furnishing a service to a beneficiary during a CJR episode, where the participant hospital or such entity or individual: (1) Does not comply with the CJR model requirements; or (2) is identified as noncompliant via CMS' monitoring of the model, or (3) engage in behavior related to any of the reasons previously described that apply to the BPCI initiative.

We are finalizing this proposal with a modification to clarify that CMS will enforce the model's requirements against participant hospitals. Given that participant hospitals may receive reconciliation payments, and choose to distribute or share those payments with other providers or suppliers (''CJR collaborators'') we believe that enhanced scrutiny and monitoring of participant hospitals is necessary and appropriate. We also believe that by making the participant hospital responsible for compliance with the CJR model, CMS will be indirectly ensuring CJR collaborators compliance, in addition to any direct monitoring by HHS (including CMS and OIG) of providers and suppliers that are CJR collaborators. However, because entities and individuals that are not participant hospitals are not actually participants in the CJR model, we will hold the participant hospital responsible for their own and their CJR collaborators' compliance with applicable model requirements. Thus, where CMS, HHS, or its designees discovers an instance of noncompliance by a CJR collaborator with the requirements of the CJR model, CMS, HHS, or its designees may take remedial action against the participant hospital, which may include requiring the participant hospital to terminate a collaborator agreement with a CJR collaborator and prohibit further engagement in the CJR model by that CJR collaborator. Participant hospitals and CJR collaborators remain subject to all existing requirements and conditions for Medicare participation not otherwise waived for this model under section 1115A(d)(1) of the Act.

We are finalizing our proposal to give CMS the option to use any one or more of the following enforcement mechanisms for participant hospitals in CJR. These enforcement mechanisms may be instituted and applied in any order, as is consistent with other CMS models:

- Warning letter—We are finalizing our proposal to give CMS the authority to issue a warning letter to participant hospitals to put them on notice of behavior that may warrant additional action by CMS. This letter will inform participant hospitals of the issue or issues identified by CMS leading to the issuance of the warning letter.
- Corrective Action Plan—We are finalizing our proposal to give CMS the authority to request a corrective action plan from participant hospitals. We are finalizing our proposal the following requirements for corrective action plans:

++ The participant hospital will be required to submit a corrective action plan for CMS approval by the deadline established by CMS.

++ The corrective action plan will address what actions the participant hospital must take within a specified time period to correct the issues identified by CMS.

++ The corrective action plan may include provisions requiring that the participant hospital terminate collaborator agreements with CJR collaborators that are determined by CMS, HHS, or its designees to be engaging in activities involving noncompliance with the provisions of this final rule, engaged in fraud or abuse, providing substandard care, or experiencing other integrity problems.

++ The participant hospital's failure to comply with the corrective action plan within the specified time period could result in additional enforcement action, including: (1) Termination; (2) automatic forfeiture of all or a portion, at CMS' discretion, of any reconciliation payments as that term is defined in section III.C. of the proposed rule; or (3) a combination of such actions.

- Reduction or elimination of reconciliation amount—We are finalizing our proposal to give CMS the authority to reduce or eliminate a participant hospital's reconciliation payment based on noncompliance with the model's requirements, negative results found through CMS' monitoring activities, or the participant hospital's noncompliance associated with a corrective action plan (as noted previously). For example, where CMS requires a participant hospital to submit a corrective action plan, the result of the participant hospital's failure to timely comply with that requirement could be a 50 percent reduction in the reconciliation payment due to the participant hospital at the end a performance year, where the participant hospital's reconciliation report reflects a reconciliation payment.

Where the participant hospital's reconciliation report reflects a repayment amount, forfeiture of a reconciliation payment would not be an option for that performance year. Therefore, we are finalizing our proposal to add 25 percent to a repayment amount on a reconciliation report, where the participant hospital fails to timely comply with a corrective action plan or is otherwise noncompliant with the model's requirements. This provision includes noncompliance by CJR collaborators with the model's requirements.

- Termination from the model—Given this model's provisions outlining the participation of hospitals in the model, we believe that, in contrast to other CMS models, termination from the CJR model would contradict the model's design. Nonetheless, we believe it is important for CMS to have this enforcement mechanism as an available option, and thus we are finalizing our proposal that CMS may terminate a participant hospital from the CJR model if the participant hospital, or its CJR collaborator that has a collaborator agreement with a participant hospital and performs functions or services related to CJR activities, fails to comply with any of the requirements of the CJR model or is noncompliant in other respects, which are discussed in detail later in this section. These areas of noncompliance are set forth in regulation at § 510.410(b)(1).

The effect of termination from the model is that the hospital would no longer be a participant hospital in the CJR model. We note, however, that any information collected by CMS in relation to termination of a hospital from the model would be shared with our program integrity colleagues at HHS, the Department of Justice, and their designees. Should a participant hospital, or one of its CJR collaborators, be noncompliant with the requirements of the CJR model or engage in unlawful behavior related to participation in the CJR model, we note that such information could be used in proceedings unrelated to the enforcement mechanisms in this section.

Where a participant hospital is terminated from the CJR model, we are finalizing our proposal that the hospital would remain liable for all repayment amounts from episodes of care that occurred prior to termination. CMS may terminate a participant hospital from the CJR model when the participant hospital, or its CJR collaborator performs functions or services related to CJR activities, fails to comply with any of the requirements of the CJR model. CMS may terminate a participant hospital's participation in the model, or require a participant hospital to terminate a collaborator agreement with a CJR collaborator for reasons including, but not limited to the following:

- The CJR participant hospital, a CJR collaborator that has a collaborator agreement with the participant hospital, or an individual or entity participating in the CJR model under the participant hospital does any of the following:

++ Takes any action that threatens the health or safety of patients; avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20; or avoids patients on the basis of payer status.

++ Is subject to sanctions or final actions of an accrediting organization or

federal, state or local government agency that could lead to the inability to comply with the requirements and provisions of this final rule.

++ Takes any action that CMS determines for program integrity reasons is not in the best interests of the CJR model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the CJR model.

++ Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions.

++ Is subject to action involving violations of the physician self-referral prohibition, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model.

Finally, we are clarifying our proposal that CMS may terminate the CJR model for reasons including but not limited to the following:

- CMS determines that it no longer has the funds to support the CJR model.
- CMS terminates the model pursuant to section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review. This provision is set forth in regulation at new § 510.900

*D. Quality Measures and Display of Quality Metrics Used in the CJR Model*

1. Background

a. Purpose of Quality Measures in the CJR Model

In section III.D.1.a. of the proposed rule, we stated that the priorities of the National Quality Strategy [53] include making care safer and more affordable, promoting effective communication and coordination as well as engaging patients and families in their care. We also stated our belief that quality measures that encourage providers to focus on the National Quality Strategy priorities will ultimately improve quality of care and cost efficiencies. In section III.C.5. of the proposed rule, we proposed that in order for a hospital in the model to receive a reconciliation payment for the applicable performance year, the participant hospital's measure results must meet or exceed certain thresholds compared to the national hospital measure results calculated for all HIQR-participant hospitals for all three measures for each performance period. More specifically, for performance years 1 through 3, a participant hospital's measure results must be at or above the 30th percentile of the national hospital measure results calculated for all hospitals under the HIQR Program for each of the three measures for each performance period (for a detailed discussion see section III.C.5.b. of the proposed rule). For performance years 4 and 5, a participant hospital's measure results must be at or above the 40th percentile of the national hospital measure results (for a detailed discussion see section III.C.5.b. of the proposed rule). In section III.D. of the proposed rule we proposed and described quality measures that will be used for public reporting and to determine whether a participant hospital is eligible for the reconciliation payment under the model. We proposed a Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) complications measure and readmissions measure, as well as a patient experience survey measure for the model. We stated that these measures assess the priorities of safer care, transitions of care and effective communication, and engagement of patients in their care, respectively. Specifically, we proposed the following three CMS outcome measures:

- The Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (as referred to as THA/TKA Complications measure (NQF #1550)).
- The Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmissions measure (NQF #1551)).
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166).

We indicated in the proposed rule that these measures are fully developed for the inpatient hospital settings, are endorsed by the National Quality Forum (NQF), and recommended by the NQF Measure Application Partnership (MAP) with subsequent implementation in the HIQR Program, HVBP Program, and the HRRP (see FY 2015 IPPS/LTCH final rule 79 FR 50031, 50062, 50208 through 50209, and 50259). These measures are also publicly reported on the *Hospital Compare* Web site.

We previously stated that an important purpose of the proposed quality measures for the model is to provide transparent information on hospital performance for the care of patients undergoing eligible elective joint replacement surgery, and to ensure that care quality is either maintained or improved. The proposed measures assess the following key outcomes for patients undergoing elective joint replacement surgery:

- Serious medical and surgical complications.
- Unplanned readmissions.
- Patient experience.

In the proposed rule we discussed the impact of THA/TKA procedures on complications and unplanned readmissions. We noted that THA/TKA procedure complications and readmissions result in excess inpatient and PAC spending, and reductions in these undesirable events will improve patient outcomes while simultaneously lowering healthcare spending. To this end, we also stated that the THA/TKA Complications measure (NQF #1550) will inform quality improvement efforts targeted towards minimizing medical and surgical complications during surgery and the postoperative period, and that the THA/TKA Readmissions measure (NQF #1551) captures the additional priorities of care provided in the transition to outpatient settings and communication between patients and providers, during and immediately following inpatient admission. We stated our belief that improved quality of care, specifically achieved through coordination and communication among providers, and with their patients and their caregivers, can favorably influence performance on these measures. We continue to believe improvement in measure performance will also mean improved quality of care and reduced cost.

We also stated in the proposed rule our continued focus on patient experience during hospitalizations, and our belief that the HCAHPS Survey measure (NQF #0166) provides not only the opportunity for patients to share their LEJR hospital experience, but also for hospitals to improve quality of care based on patient experience. For example, the HCAHPS Survey measure (NQF #0166) ''categories of patient experience'' specifically provides areas (for example, communication with doctors and nurses, responsiveness of hospital staff, pain management) in which a hospital could improve transition of care and increase patient safety (80 FR 41282). We also

[53] National Quality Strategy. Working for Quality: About the National Quality Strategy. Available at: *http://www.ahrq.gov/workingforquality/about.htm#develnqs*. Accessed on April 15, 2015.

summarized that the HCAHPS survey includes measures related to nurse and physician communication, pain management, timeliness of assistance, explanation of medications, discharge planning and cleanliness of the hospitals to provide specific areas for hospitals to improve on,[54] and indicated in the proposed rule the some of the specific questions on provider communication included the following:

- How often the patient believed providers listened carefully to his or her questions?
- Whether the purpose of medications and associated adverse events were explained?
- Whether discussions on post-discharge instructions and plans occurred so that the patient had a clear understanding of how to take medications and an understanding of his or her responsibilities in managing his or her health post-discharge?

In the proposed rule we addressed how these areas of patient experience would be invaluable to improving hospital quality of care. We noted that Manary, *et al.*[2] suggested that by focusing on patient outcomes, hospitals could improve patient experience and highlighted that timeliness of measuring patient experience is important due to the potential for recall inaccuracies. We noted that administration of the HCAHPS Survey measure (NQF #0166) must begin between 2 and 42 days after discharge from a hospital.

We also briefly addressed the concern regarding the question of whether there is a relationship between patient satisfaction and quality of surgical care. We addressed this question by noting the work of Tsai, *et al.*[55] We noted that Tsai *et al.* recently assessed patient satisfaction using the HCAHPS survey results and correlated quality performance using nationally implemented structural, process and outcome surgical measures (that is, structural, process and outcome surgical measures in the HVBP program and the HRRP). The study found a positive relationship between patient experience of care and surgical quality of care, among the 2,953 hospitals that perform six high cost and high frequency surgical procedures that are also associated with morbidity and mortality in Medicare beneficiaries. The study also included hip replacement procedures, and specifically noted that those hospitals with high patient satisfaction also had high performance on nationally implemented surgical quality measures (such as the Surgical Care Improvement Project measures and 30-day risk-adjusted readmission and perioperative mortality outcome measures). We noted that although the HCAHPS Survey measure (NQF #0166) is not specific to joint replacements, the survey provides all patients the opportunity to comment on their hospital experience, including patients who have received LEJRs, having all patients responding to the survey helps to inform hospitals on areas for improvement. We also indicated that while HCAHPS scores are aggregated at the hospital level, the surgical service line is one of three service lines encompassed by the survey.[56]

Finally we shared our goal to strive to align as many measures and programs as is feasibly possible, and stated our belief that proposing fully developed measures that are used in other CMS hospital quality programs will minimize the burden on participant hospitals for having to become familiar with new measures, while still allowing us to appropriately capture quality data for the model.

The following is a summary of the many comments received and our responses.

*Comment:* We note multiple stakeholders supported the proposed three measures and the THA/TKA voluntary data submission in the CJR model. Others specifically supported the mandatory nature of the measures because it encourages hospitals to improve quality of care for THA/TKA patients.

*Response:* We appreciate support by multiple stakeholders for the measures and the THA/TKA voluntary data submission in the CJR model.

*Comment:* A few commenters indicated concerns over beneficiary protections and potential for stinting of care as it relates to the financial incentives of the CJR model, and there were concerns about the three proposed measures being insufficient metrics to assess CJR beneficiary health care outcomes, such as a return to activities of daily life. Other beneficiary protection concerns included the potential unintended consequences of encouraging: (1) Inappropriate care shifting by providers within the 90-day post-operative day window for the THA/TKA Readmissions measure (NQF #1551); (2) readmissions related to infection, hematoma, pulmonary embolus following THA or TKA replacement which may not be controllable despite adherence to best practices should not be included in the episode of care; and (3) providers may decrease or deny access to care for patients with comorbidities, in order to improve rates on the THA/TKA Readmissions measure (NQF #1551) and THA/TKA Complications measure (NQF #1550).

*Response:* We appreciate the commenters' concerns about potential unintended consequences for beneficiaries resulting from implementation of the three proposed measures. We note that the CJR model does address beneficiary protections, access to care, quality of care, and delayed care, as discussed in section III.F. of this final rule.

Regarding the concern about the proposed measures being inadequate to determine whether the care provided to the patient was sufficient to promote an adequate recovery and return to activities of daily life, we acknowledge that the proposed measures do not specifically address activities of daily living, but we note that the THA/TKA PRO data collection does include survey instruments (that is, PROMIS and VR–12 surveys) that assess activities of daily life information and pain management. Through this voluntary initiative, we believe we will begin to address this gap in the current measure set for the CJR model.

Regarding the concern about the potential unintended consequences of care shifting by providers to prevent poor performance on the THA/TKA Readmissions measure (NQF #1551), we note from the beneficiary protection perspective that the model allows beneficiaries to choose their providers and suppliers, and has processes where CMS will be monitoring claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline, to determine whether complex patients are being systematically excluded. We will also be publishing this data as part of the model evaluation to promote transparency and an understanding of the model's effects. We note from a quality measurement perspective that the readmission measure assesses unplanned readmissions in the 30 days following discharge from an eligible hospitalization. As previously discussed in the context of the HIQR Program (77 FR 53521), the measure uses a 30-day timeframe because it is a clinically meaningful and sufficient time period for hospitals to show the result of their

[54] Manary MP, Boulding W, Staelin R, Glickman SW. The Patient Experience and Health Outcomes. New England Journal of Medicine. Jan 2013; 368(3):201–203.

[55] Tsai TC, Orav EJ, Jha AK. Patient Satisfaction and quality of surgical care in US hospitals. Annals of Surgery. 2015; 261:2–8.

[56] Giordano LA, Elliott MN, Goldstein E, Lehrman WG, Spencer PA. Development, Implementation, and Public Reporting of the HCAHPS Survey. Medical Care Research and Review. 2010;67(1):27–37.

efforts to reduce readmissions. However, we believe that hospitals should be monitored for shifts in patient care. In the context of the Hospital Readmission Reduction Program (77 FR 53376), we acknowledged stakeholders' concerns for unintended consequences of inappropriate shifting of care, increased morbidity and mortality and other negative unintended consequences for patients. We stated our commitment to monitor the outcome measures and assess unintended consequences over time. In addition to internal monitoring of hospital performance and potential unintended consequences, we specifically publish online each year the Medicare Hospital Quality Chartbook (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html*). This annual Chartbook provides new information about recent trends and variation in condition specific and surgical procedure outcomes by location, hospital characteristics, and patient disparities. In the FY2016 IPPS/LTCH final rule (80 FR 49674 through 49690), we finalized reporting of two new excess days in acute care measures that will complement the existing readmission measures by providing addition information and insight about patients that return to the hospital for emergency department visits, observation stays or inpatient readmissions after hospitalization for acute myocardial infarction and heart failure.

Regarding the concern that readmissions related to infection, hematoma, and pulmonary embolus following THA or TKA replacement may not be controlled despite adherence to best practices, we acknowledge that we do not expect hospitals to achieve a hospital-level THA/TKA RSRR of zero, but instead expect hospitals to seek and implement processes to improve their annual THA/TKA RSRR. We base this belief on the need to improve THA/TKA RSRRs, based on Medicare FFS administrative claims data from July 1, 2011 to June 30, 2014, which revealed a median RSRR of 4.8 percent with a range of 2.6 percent to 8.5 percent. A range of 2.6 percent to 8.5 percent suggests room for improvement. Further, we note that we measure all-cause readmission, including readmission for conditions such as infection, hematoma, and pulmonary embolus, rather than a narrowly defined set of conditions, to assess performance for several reasons. First, from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care after an acute hospitalization. Secondly, readmissions not directly related to hip/knee replacement may still be a result of the care received during hospitalization for the procedure. For example, a patient who underwent a THA/TKA procedure who develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to treat this readmission as unrelated to the care the patient received during the index hospitalization. Furthermore, the range of potentially avoidable readmissions also includes those not directly related to the initial hospitalization, such as those resulting from poor communication at discharge or inadequate follow-up. In addition, readmissions for rare reasons completely unrelated to hospital care, such as car accidents involving the patient as a passenger, are likely to be distributed randomly across hospitals and are not expected to introduce bias into the measure results.

We appreciate the concern expressed by the commenter that surgeons may choose not to operate on patients who have comorbid conditions in order to improve the hospital's performance on the readmission measure. We had similar concerns about this potential unintended consequence, and for this reason the THA/TKA Readmissions measure (NQF #1551) risk adjusts for patients' risk factors, thereby taking into account case mix differences across providers. Adjusting for case mix is an important aspect for measuring a RSRR that accurately reflects factors that can confound an outcome rate when not adequately adjusted.

Finally, we do not believe that the proposed measures are insufficient metrics to assess CJR model patients. We note that hospitals are the unit of analysis for this model and that the proposed measures are hospital-level measures. We believe that these hospital-level measures do assess how hospitals provide care for THA/TKA patients since the measures assess complications, which are costly, and assess patients' perspectives on their hospital experience, which also includes patient feedback on communication with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment, quietness of the hospital environment, and transition to post-hospital care. While we acknowledge that the proposed measures do not include reported functional outcomes, we have proposed the THA/TKA voluntary data submission initiative to begin to assess post-operative functional outcomes. To our knowledge a hospital-level risk-adjusted patient-reported functional outcome measure using a non-proprietary instrument to assess the measure outcome does not exist nor did we receive any suggestions from the public for measures that fit this description. We anticipate including hospital-level risk-adjusted patient-reported functional outcome measure in years 4 and 5 of this model.

*Comment:* Some commenters expressed concern that the current CJR model measure set does not adequately protect patients, since the measure set does not include what LEJR patients care most about, which is being able to walk following their joint replacement surgery and minimizing post-surgical pain. These commenters suggested that the CJR model require measures that address assessment of how well pain was managed, the patient's pain experience and the inclusion of a functional measure that meaningfully assesses the ability to walk after surgery.

*Response:* We note that the three proposed measures address inpatient care and that outpatient care will begin to be assessed by the by the voluntary data submission for the THA/TKA patient-reported outcome-based measure currently in development (80 FR 41284 through 41289). The HCAHPS Survey measure (NQF #0166) was created to capture many different aspects of care experienced by inpatients. The proposed HCAHPS Survey measure (NQF #0166) specifically assesses how well hospital staff help patients manage pain, how responsive hospital staff are to patients' needs and how well the patients are prepared for the transition to post-hospital care. Because the HCAHPS Survey measure (NQF #0166) begins to address areas of pain management and ambulation by assessing transition to post-hospital care, and because hospitals are very familiar with the HCAHPS Survey measure (NQF #0166), we believe that this measure is a good starting point to assess and quantify how well patients' pain was managed and whether patients' pain experience was assessed during a hospitalization. Furthermore, we believe that the THA/TKA voluntary PRO data submission portion of the CJR model does begin to address the concerns of patients, as this measure in development included patients as members of the Technical Expert Panel convened by the measure developer. The Technical Expert Panel, which included patient members, provided input into all aspects of the

development of this measure, including the proposed pre-operative and post-operative THA/TKA voluntary data elements (80 FR 41285 and 41286). We also note that patient participation was integral to the creation of the THA patients' Hip disability and Osteoarthritis Outcome Score (HOOS) and TKA patients' Knee injury and Osteoarthritis Outcome Score (KOOS) surveys. For these reasons, we believe the HCAHPS Survey measure (NQF #0166) and the HOOS and KOOS surveys in the voluntary submitted data for the THA/TKA patient-reported outcome based measure do address the perspective of patients regarding pain management, the quality of pain care and the functional assessment of walking post-primary elective THA and TKA. Finally, we emphasize we anticipate that a fully specified and tested THA/TKA patient-reported outcome-based performance measure will be included in years 4 and 5 of the CJR model.

*Comment:* Many commenters requested that CMS assess patient experience regarding pain experience, pain management and ambulation. In addition, they requested that measures be instituted that assess pain management frequently to counterbalance the economic interests of hospitals. Some shared that pain measures should be conducted every day and long-term measures be conducted quarterly during the first post-operative year.

*Response:* We appreciate the suggestions to expand the measure set for the CJR model to include inpatient and outpatient experience regarding pain management and ambulation. We note that the HCAHPS Survey measure (NQF #0166) does include inpatient pain management experience and that the THA/TKA voluntary data submission also addresses post-operative ambulation. To our knowledge, there are no other hospital-level risk-adjusted outcome measures for patient experience that assesses pain experience, pain management and ambulation. As the CJR model continues to refine its measure set we will consider the recommendation for pain management patient experience of care measures that are applied frequently to counterbalance hospital economic interests.

*Comment:* Commenters suggested placing a greater weight on measures that address assessment of how well pain was managed, the patient's pain experience and the inclusion of a functional measure that meaningfully assesses the ability to walk after surgery.

*Response:* As discussed in a prior related comment, we note that the HCAHPS Survey measure (NQF #0166) specifically assesses how well hospital staff help patients manage pain, how responsive hospital staff are to patients' needs and how well the patient was prepared for the transition to post-hospital care. We also note that section III.C.5.(c)(ii) of the proposed rule discussed an alternative link to quality and payment provided a weight of 30 percent to the HCAHPS Survey measure (NQF #0166). We refer reviewers to section III.C.5. of this final rule for responses to this comment from a payment perspective for a full discussion of the finalized policy for reconciliation payment based on measure performance. From an HCAHPS Survey measure (NQF #0166) perspective, we note that the HCAHPS survey captures the inpatient experience from the patient's perspective and the survey must be conducted within 48 hours and 6 weeks of discharge. We also note that the THA/TKA voluntary PRO data submission includes both pre-operative surveys covering 90 to 0 days of care, and post-operative surveys focus on days 270 to 365 post-surgery for the primary elective THA/TKA procedure.

*Comment:* Many commenters supported the proposed three measures, and specifically the mandatory nature of the measures and the proposed weights in the reconciliation payment composite quality score methodology (80 FR 41241 Table 8).

*Response:* We appreciate the support of the mandatory nature of the three proposed measures in the CJR model.

*Comment:* We received comments regarding how the CJR model links quality and payment. The comment was made based on the already low complication and readmission rates, with the suggestion to have incentive payments for sustained top performance.

*Response:* For a discussion of how the CJR model links quality and payment and incentive payments, we refer readers to section III.C.5. of this final rule.

Regarding that portion of the comment stating that the THA/TKA complications and readmissions rates are already low, we note that there is still room for improvement related to the complication and readmission rates for primary elective THA/TKA procedures. As previously noted in the preamble the median hospital-level primary elective THA/TKA RSCR's for April 1, 2011 through March 31, 2014 was 3.1 percent with a range from 1.4 percent to 6.9 percent. Similarly, the data on the THA/TKA RSRR for a 3-year period (July 1, 2011 to June 30, 2014) revealed a median RSRR of 4.8 percent with a range of 2.6 percent to 8.5 percent. We believe both sets of data with the median RSCR and RSRR and the associated ranges, rather than suggesting a low rate, suggest room for improvement in preventing complications. Finally, we believe, from a patient's perspective, that readmissions and complications are undesirable outcome of care, and therefore providers should strive to improve all aspects of health care that influence the occurrence of complications and readmissions so that the median RSCR, RSRR, and their ranges consistently improve over time.

*Comment:* A commenter while supporting the three proposed measures and the THA/TKA voluntary data submission, indicated that CMS needs to provide a stronger financial incentive and compensation for additional costs related to submission of THA/TKA voluntary PRO data.

*Response:* We appreciate the support of the three proposed measures and the THA/TKA voluntary PRO data submission. Regarding the comment indicating that CMS needs to provide a stronger financial incentive and compensation for additional costs related to submission of THA/TKA voluntary data, we refer readers to section III.C.5.b.(5)(c)(iii) of this final rule.

*Comment:* Many commenters suggested various ways to adjust the robustness of the current proposed measure set for the CJR model. Suggestions included that we (1) add more patient-reported functional measures that address ambulation and pain management, such as specific functional measures like Functional Change: Change in Motor Score (NQF #2287), CARE: Improvement in Mobility (NQF #2612) and CARE: Improvement in Self Care (NQF #2613); (2) add measures used in the BPCI model 2, including the all-cause mortality and the emergency department use without hospitalization; (3) have appropriateness measure (measuring appropriateness of care at the beginning of the episode) or a utilization measure (assessing utilization patterns and case mix as part of the evaluation); (4) have measures specific to assess care provided in a continuum consistent with the episode of care and inclusive of the PAC settings in general and specifically for home health agencies; (5) have a measure set that is similar to the Physician Quality Reporting System (PQRS) Total Knee Replacement Measures Group; and (6) incorporate Unique Device Identification (UDI) of

hip and knee replacements into administrative claims data since it would benefit the CJR model by providing better information to hospitals on device quality and costs, and could enhance data to CMS to ensure quality.

*Response:* We appreciate these suggestions for ways to increase the robust nature of the CJR model measure set.

We appreciate the suggestion for the Functional Change: Change in Motor Score (NQF #2287), as it helps us to be sure we have considered all possible measures. We note that the suggested measure of Functional Change: Change in Motor Score (NQF #2287) was developed for use in inpatient rehabilitation facilities (IRFs). Specifically, the Functional Change: Change in Motor Score (NQF #2287) measure is based upon the Functional Independence Measure (FIM), which is intended for use with nursing home residents and IRF patients and assesses functional status items relevant to that patient population, including Feeding, Grooming, Dressing Upper Body, Dressing Lower Body, Toileting, Bowel, Expression, Memory, Transfer to/from Bed/Chair/Wheelchair, Transfer to/from Toilet, Locomotion and Stairs. Since the unit of analysis is not acute care hospitals, this measure would not be appropriate for CJR model. We note that the TEP convened by the measure development contractor, which included clinical and technical experts as well as patients, believed the HOOS/KOOS, VR–12 and PROMIS-Global instruments assessed more meaningful pain and function outcomes at 270 to 365 days after elective primary THA/TKA patient population, which led to our proposal of the HOOS/KOOS, VR–12 and PROMIS-Global instruments. Additionally, we note that the suggested Functional Change: Change in Motor Score (NQF #2287) measure does not focus on acute care hospital care of THA/TKA patients, which is important since CJR hospitals are the unit of analysis for this model. We acknowledge the importance of assessing patient-reported functional changes, which is why we also proposed the THA/TKA voluntary data for patient-reported functional outcomes. We note that the voluntary submission of THA/TKA voluntary data for patient-reported functional outcomes using the proposed survey tools will begin to address functional outcomes of ambulation, thereby adding to the HCAHPS Survey measure (NQF #0166), which assesses inpatient pain management.

Regarding the suggestion to use BPCI model 2 measures that assessed all-cause mortality and the emergency department use without hospitalization. We note that these were not measures but instead interim analyses performed to assess these aspects of the model. Since the CJR model is specific to LEJR we chose to identify measures that were not only specific to these procedures but were risk-adjusted and developed for acute care hospitals. We also chose the proposed measures for the reasons outlined in Background sections of III.D.1.a., III.D.2.a., III.D.2.b. and III.D.2.c.

Regarding the suggestions for specific PAC measures (for example, CARE: Improvement in Mobility (NQF #2612) and CARE: Improvement in Self Care (NQF #2613)), and the general comment to add measures that: (1) Address care across the continuum of the CJR model episode of care; (2) are specific to the PAC setting; and (3) and/or are similar to the Total Knee Replacement (TKR) Measures Group found in the PQRS, we note that for this CJR model we restricted our choice of measures to hospital-level measures given that attribution of the model is at the hospital level, and specifically to risk-adjusted hospital-level outcome measures. In addition, although these suggested functional outcome measures assess functional change in the PAC setting and potentially across the continuum of the episode of care, they are not specific to the THA/TKA procedure patients in our 5-year CJR model.

Regarding the suggestion to include an appropriateness measure or a utilization measure, we are unaware of existing consensus guidelines as to what pre-operative level of pain or functional disability justifies elective primary THA or TKA procedures. Therefore, we believe it is premature to create an appropriateness measure without engaging with patients and providers to define appropriateness. Further, while we have developed a measure of Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA), this measure will not have been publicly reported until July 2016 and was therefore not considered for the CJR model at this time. We will consider changes to the quality measure components for the CJR during future rulemaking as appropriate.

Regarding the suggestion to consider device selection in measures, we understand this comment to be about post-marketing surveillance of medical devices used in THA/TKA procedures. We note that the addition of device selection and the ability to capture it through administrative claims codes will impact many other measures and CMS programs. We will evaluate this concern in the future as needed.

*Comment:* A single commenter requested that quality measurements between hospitals and physicians should be delinked when determining eligibility for savings, so that high-performing physicians are eligible for savings even when a hospital is underperforming.

*Response:* We note that section III.B. of the proposed rule provides a detailed summary of the episode definition (80 FR 41212) and a detailed discussion on why hospitals are the unit of analysis for the CJR model episode of care and the proposed quality measures. We refer reviewers to section III.C. of this final rule for a discussion on how physicians could influence their eligibility for savings under the CJR model. We note that the quality measures are all hospital-level since acute care hospitals are the unit of analysis for quality measures and that physicians will continue to be assessed through programs such as the Physician Quality Reporting System. As the CJR model undergoes refinement in the subsequent years, if it becomes reasonable and feasible to implement physician-level measures, we will consider implementing such changes to the CJR model through notice-and-comment rule making.

*Comment:* Some stakeholders recommended that CMS, over time, require information about patients' changes in function so that this data can be used as an outcome measure. They also agreed with the MedPAC's public comment that CMS consider collection of the same information on function that is required of PAC providers to comply with the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014.

*Response:* We note that CMS recently finalized an application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015) in multiple PAC settings for FY 2018 and subsequent years (for the IRF setting, see 80 FR 47100; for the LTCH setting, see 80 FR 49739). This is a process measure that requires the collection of admission and discharge functional status data using standardized clinical assessment items, or data elements that assess specific functional activities, that is, self-care and mobility activities across

PAC settings. In addition to proposing a process-based measure for the domain in the IMPACT Act of functional status, cognitive function, and changes in function and cognitive function, we also intend to develop outcomes-based quality measures, including functional status and other quality outcome measures, to further satisfy this domain. Although these measures will assess functional change for each care setting as well as across care settings, they will not be specific to the THA/TKA procedure patients in the 5-year performance period of the CJR model.

Notwithstanding the important changes instituted by the IMPACT Act, we note that current patient function data collected in various PAC PPSs gather patient function data from the provider's perspective, that is, these data are provider-reported, while the proposed THA/TKA voluntary data submission collects functional data from the patient's perspective (that is, patient-reported). We are committed to prioritizing patient-reported outcomes as these data are likely to focus attention on the most patient-centered care feasible. We also note that the PAC data are collected after the THA/TKA procedure and therefore cannot be used to assess the patient's response to this elective intervention. In addition, these data are collected at admission and discharge from PAC settings. Therefore, these data are not captured over a standard time period, and changes in these assessments may not reflect differences in quality of care across providers. Finally, these assessments are administered to patients during the acute recovery phase following these procedures, as they are intended to assess the quality of care provided during the immediate post-operative rehabilitation period. Patient function during this period is usually restricted by the responsible physician for a period of weeks to ensure prosthetic joint stability; patients' activities are then advanced as tolerated over time. Therefore, short-term functional assessments are inadequate for capturing the full patient outcomes after these procedures, and the Technical Expert Panel convened by our measure development contractor strongly urged post-operative data be collected at least 9 months after surgery. For all of these reasons, we believed the proposed voluntary PRO data collection specifications better reflect outcomes meaningful to patients undergoing elective joint replacement surgery and better assess hospital-level quality of care. We also note that depending on the quality measure used and the setting in which the measure is applied, the measure may not allow collection of identical patient function data across all settings, since an applicable patient-related functional data element in one setting may not necessarily be applicable in another setting. For example, if the intent of a patient functional measure is to assess the frequency of post-operative infections for hospitals, the same measure may not be applicable to an IRF or a HHA.

Finally, we note that we are committed to considering the implementation of quality measures that are standardized and interoperable across PAC and hospital settings using standardized patient assessment data.

*Comment:* Some commenters believed that linking quality measure performance to eligibility for reconciliation payment in order to ensure continued attention to quality of care throughout the duration of the program and promote collaboration among all parties involved in beneficiaries' care approach fails to reflect the quality of care to be delivered in the context of the model. These commenters believe that the currently proposed methodology to determine performance on quality measures and linkage to reconciliation payment eligibility uses arbitrary distinctions in performance among hospitals that are not borne out by the data or even by CMS's own method of rating performance on the *Hospital Compare* Web site. Further, these commenters recommend that we adopt a balanced approach by using a methodology similar to the confidence intervals used in *Hospital Compare* that distinguishes performance based on the three categories of comparison to the national average. They recommended using only the performance on THA/TKA Complications measures (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) to determine if a hospital is eligible for reconciliation payment. Specifically, they recommended that if performance on both of these two measures is both statistically worse than the national average, then a hospital should not be eligible for reconciliation payment. Additionally, other commenters agreed that use of measure result point estimates to determine percentiles may not be appropriate because—(1) The measures are a ratio comparing observed to expected, where expected is based on the national performance. An individual hospital's performance should be assessed within confidence intervals as the measure was originally specified, tested, and endorsed by the NQF; and (2) they believe that there may not be a distinguishable difference in the performance of hospitals at the 50th percentile and the 30th percentile. These commenters specifically recommended a solution that uses confidence intervals similar to how outcome measure results are presented in *Hospital Compare,* where hospitals are grouped into ''no different than the national rate,'' ''better than the national rate,'' or ''worse than the national rate.'' Hospitals that are ''no different than the national rate'' or ''better than the national rate'' should automatically be deemed eligible for any potential savings.

*Response:* We appreciate these comments and refer reviewers to section III.C.5.b.(5)(c)(iii) of this final rule for a detailed response to these concerns.

*Comment:* A single commenter sought guidance on how a hospital system will measure quality of care delivered by outside agencies.

*Response:* We understand the commenter to be referring to guidance on measuring the quality of care delivered by PAC providers. CMS has several PAC quality and payment programs with quality metrics. We encourage hospitals to review the—(1) IRF Program Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/index.html*; (2) Long-Term Care Hospital Quality Reporting Program Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html?redirect=/LTCH-Quality-Reporting/*; and (3) Skilled Nursing Facility Quality initiative Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html.* At this time, these three PAC quality programs do not report quality measure results on a Compare Web site. For Home Health Agencies please see: *https://www.medicare.gov/homehealthcompare/*) and for Nursing Homes please see ''about the data'' tab at *https://www.medicare.gov/nursinghomecompare/* for an explanation of the measures used in these programs. We also refer the public to Data.Medicare.gov (see: *https://data.medicare.gov/*) for a list of measures in these two programs. Both the Home Health Compare and Nursing Home Compare Web sites explain their respective data sources and may be of help in guiding hospital systems that are interested in measuring quality of care delivered by home health agencies and nursing homes. For example, in the Home Health Compare Web site the section entitled ''About the Data''

indicates that data come from the following two sources: (1) CMS's health inspection database—Includes the nursing home characteristics and health deficiencies issued during the 3 most recent state inspections and recent complaint investigations. Data about staffing and penalties made against nursing homes also come from this database; and (2) National database known as the Minimum Data Set (MDS)—Data for quality measures come from the MDS Repository. The MDS is an assessment done by the nursing home at regular intervals on every resident in a Medicare- or Medicaid-certified nursing home. Information is collected about the resident's health, physical functioning, mental status, and general well-being. These data are used by the nursing home to assess each resident's needs and develop a plan of care. Understanding how CMS and states assess the care of home health agencies and becoming familiar with the guidelines that CMS sets for home health agencies can help to inform individual hospitals or hospital systems on how to assess quality of care by PAC agencies.

*Comment:* Some commenters had concerns regarding the proposed requirement that hospitals pass all three thresholds in order to realize and receive payment for savings. They expressed concern that such a requirement will have the effect of filtering out close to 60 percent of the participants, and believe that the proposed measures act as a triple filter and are biased against teaching hospitals and urban hospitals. They believe that the HCAHPS Survey measure (NQF #0166) is particularly biased against teaching and urban hospitals. They believe that CMS should establish a quality metric or a set of metrics that more accurately reflect care during the performance period, that are based on a set threshold, and that do not remove a certain percentage of the participants.

*Response:* In section III.C.5.b.(5)(c). of the proposed rule, we discussed how we would link performance on quality measures with the reconciliation payments, including the proposal to use a 30 percent threshold for the first 2 years of the model, followed by a 40 percent threshold for years 3–5 of the model. We refer reviewers to section III.C.5. of this final rule for a full discussion regarding this proposal and our final policy.

In section III.D. of the proposed rule (80 FR 41276), we discussed, in detail, the three proposed measures. From a measure perspective, we believe that the proposed measures (80 FR 41276 through 41290) of the THA/TKA Complications measure (NQF #1550), THA/TKA Readmissions (NQF #1551) and the HCAHPS Survey measure (NQF #0166) all accurately reflect the care provided by hospitals and their services as defined in the episode definition proposed in section III.B. of the proposed rule. Additionally, we believe that the proposed THA/TKA voluntary data submission initiative (80 FR 41284 through 41289) is also appropriate for the CJR model. We believe the proposed measures are appropriate because they are risk-adjusted outcome measures which assess important patient outcomes that are consistent with the National Quality Strategy (80 FR 41276), which acknowledges that complications and readmissions are disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections, and specifically recognizes that readmissions are also a major source of patient and family stress and may contribute substantially to loss of functional ability, particularly in older patients. We believe through the HCAHPS Survey measure (NQF #0166), CMS programs continue to highlight the importance of assessing patient experience of care. While we acknowledge that the current set of proposed measures do not include assessment of patient-reported functional outcomes in PAC settings, we note that the CJR model episode of care has acute care hospitals as the unit of analysis for this model. To our knowledge a hospital-level, risk-adjusted patient-reported outcome functional measure does not exist for ready use in the CJR model. We believe that the THA/TKA voluntary PRO data submission initiative begins to address this gap in available patient-reported outcome functional measures through this model. While the proposed outcome measures and the THA/TKA voluntary PRO data submission initiative are not all inclusive of all CJR model episode of care settings, these measures address the concerns of patients. Also, since this is a test model we believe the current measures begin to inform us of ways to improve future models. We also have indicated that we will be reviewing the quality measure landscape for measures that can provide further insight on hospital-level quality of care for THA/TKA procedures.

*Comment:* A commenter was concerned that some of the savings in the CJR model will occur after discharge and that the savings associated with the post-discharge care could impact quality of care. In order to assess this potential unintended consequence, the commenter suggested as a potential future research topic that CMS consider assessing in which setting the cost savings occur and compare that result to the quality data for the associated provider. The goal would be to answer the following questions: (1) Did any other quality measures decline as a result of the cost savings; and (2) if costs increased in a particular service area, what was the impact on the quality measures? The commenter believes that by answering these questions, we would potentially have data to help CMS better align quality measures and incentives in future models. Some commenters suggested that we assess the impact of quality measures in the CJR model and especially changes in performance amongst PAC settings relative to those participant hospitals that experienced cost savings.

*Response:* We will take these suggestions into consideration as CMS assesses ways in which to improve the CJR model. We are committed to ensuring that the CJR model continues to anticipate and identify unintended consequences that may adversely impact beneficiary care.

*Comment:* Some commenters, including consumers, strongly agreed with the quality measure thresholds of 30 percent and, later, 40 percent for earning savings. These commenters believe that retaining these standards is an essential component of the demonstration that is needed to mitigate risks of reduced care or quality for consumers.

*Response:* We appreciate the support of the proposed measures and the suggestion to retain the proposed quality measure thresholds of 30 percent and, in later years of the CJR model 40 percent, in order to mitigate the unintended consequence of reduced quality of care for consumers. We are also concerned about mitigating unintended consequences for consumers and refer readers to section III.C.5. of this final rule, where the policy for use of 30 percent threshold is fully discussed, and section III.F. of this final rule, where we have outlined our intent to monitor and ensure beneficiary protection against potential unintended consequences. We appreciate the importance of mitigating risks of reduced quality of care for CMS beneficiaries by finalizing thresholds that will encourage hospitals and other PAC settings to strive for improvement on measure performance. We note that in section III.C.5.b.(5)(c)(iii) of this final rule in the composite quality scoring methodology that a 30 percent threshold

was set in order to begin receiving points for performance on a measure.

*Comment:* A few commenters urged CMS to harmonize measures so that the goals of care will be consistent across the care continuum.

*Response:* While we acknowledge that the current proposed measures are hospital-level measures, we note that acute care hospitals are the unit of analysis for this model. As the CJR model continues, we will take into consideration ways in which to add measures to the model in order to have a more robust set of measures assessing all aspects of the CJR model episode.

*Comment:* Many commenters supported the use of all three proposed measures, while many others opposed the use of proposed measures since the measure cohorts are not completely aligned with the proposed CJR model cohorts, which are based on the MS–DRGs of 469 and 470. These MS–DRGs include all LEJR and non-elective THA/TKA procedures. Those opposed to the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) noted that the measure cohorts are limited to primary elective THA/TKA patients and that the HCAHPS Survey measure (NQF #0166) applies to all inpatients. The primary concern was that the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) fail to provide insight on quality for a significant portion of the patient population included in the CJR model. A few commenters indicated that they would not be opposed to these measures if the CJR model cohorts were completely aligned with the measure cohorts. Finally, a commenter requested clarification on the implication of using the THA/TKA Complications measure (NQF #1550), which assesses primary elective procedures and does not include patients undergoing PHA procedures.

*Response:* We appreciate the comments of those that supported the proposed measures. We also appreciate commenters' concerns regarding the lack of complete alignment between the CJR model cohorts and the proposed measure cohorts. We note, however, that the goal of the CJR model and the proposed episode definition are fully discussed in section III.B. of this final rule. The implication of not aligning with the MS–DRG 469 and 470 CJR model cohorts is that it will be difficult to assess the smaller percentage of non-elective THA and TKA patients. We note that elective THA and TKA cases make up the majority of MS–DRG 469 and 470 cases. We also note that the THA/TKA Complications measure (NQF #1550) was created to assess hospital performance on THA and TKA procedures that are not only primary procedures but also elective. In addition, the measure cohort was defined, with the input of clinical experts, a nationally convened Technical Expert Panel convened by our measure development contractor and public comment, to create a clinically coherent group of patients for whom appropriate risk prediction could be accomplished. As partial arthroplasty procedures are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions, the clinical experts and other Technical Expert Panel members believed that these procedures represented a distinct clinical risk group and should therefore be excluded from the measure. As discussed in the proposed rule (80 FR 41278), THA and TKA elective procedures are commonly performed, and the associated complication rates are rare. However, because the rate of elective THA and TKA procedures continues to increase, the overall cost of elective THA and TKA procedure complications is high. Further, for patients undergoing elective procedures, the associated risks are particularly important to understand and weigh during their decision-making process. Current quality improvement measures for patients undergoing elective THA and TKA procedures are generally limited to evidence-based processes of care. Measurement of patient outcomes, such as complications, allows for a more comprehensive view of quality of care, capturing more complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment. To date, the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) are the only outcomes measures comparing hospital performance in the care of patients undergoing elective primary THA/TKA. For these reasons, we believe that using a hospital-level risk-adjusted outcome measure is the fairest way to assess quality performance for THA and TKA procedures in the CJR model participant hospitals. As with other CMS quality and payment programs and models, we are constantly monitoring for valid and reliable measures that could be considered for the CJR model. We also may explore the possibility of further measure development to address the inclusion of non-elective THA/TKA procedures.

*Comment:* Some commenters suggested that there should be adjustment to the quality framework because the CJR model does not provide enough time or data to adequately prepare for the model.

*Response:* We disagree that there is inadequate time to prepare for the model. We note for the HIQR Program that the THA/TKA Complications measure (NQF #1550) was finalized in FY 2012 IPPS/LTCH Final Rule (77 FR 53534) for implementation in FY 2015, and the THA/TKA Readmissions measure (NQF #1551) and the most updated HCAHPS Survey measure (NQF #0166) were finalized in FY 2014 IPPS/LTCH final rule (78 FR 50807). We believe hospitals have received ample time to identify ways in which to improve their performance on these three measures. In proposing these measures, we specifically considered how familiar hospitals are with the proposed measure, knowing that hospitals will have had enough time to institute appropriate changes in order to perform well on these measures.

*Final Decision:* After consideration of the public comments, we acknowledge that the current set of measures are hospital-centric in order to be consistent with the goals of this model, one of which is to encourage collaboration between providers (for example, hospitals, PAC facilities, and other types of providers) in order to achieve better care with cost savings while holding the acute care hospitals financially responsible. We recognize the gaps in the current measure set relative to other settings in which patients receive care post-operatively. However, we believe that given the current design of the test model where the hospital is the unit of analysis, that the proposed measures are well developed, hospital-level risk-adjusted outcome measures that do address patient experience and outcomes that are important to patients like complications and readmissions. Further, we believe hospitals, in comparison to other health care facilities, are more likely to have resources that will allow them to appropriately coordinate and manage care throughout the episode, and hospital staff members who are already involved in hospital discharge planning and PAC recommendations for recovery, which are key dimensions of high quality and efficient care for the episode. For these reasons, we believe it is appropriate to implement hospital-level measures. We acknowledge that as CMS gains more experience with this model, there may be future

opportunities to create a more robust set of quality measures for this model where we can broaden the scope of measures to include those applicable to PAC settings. As with any new initiative, we will continue to assess the ever-changing inventory of measures with the goal to build a more robust set of measures that support the intent of this model. We intend to continue to refine the measure set based on future public comments, any changes in the payment methodology that may require specific measures, and recommendations from the participating hospitals as CMS learns more about the impact of the model on quality improvement and cost savings.

b. Public Display of Quality Measures in the CJR Model

In section III.D.5. of the proposed rule, we stated our belief that the display of measure results is an important way to educate the public on hospital performance and increase the transparency of the model, and therefore proposed, for the model, to display quality measure results on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*). We also stated our belief that the public and hospitals are familiar with this Web site and the display of hospital quality measure information, and also noted that the public and hospitals are familiar with the proposed measures, as these measures have been displayed on the *Hospital Compare* Web site over the past few years. Finally, we indicated our intent to align the display of quality measure results and access to this data for the model with other CMS hospital quality programs by proposing to post model quality measure results and data on the *Hospital Compare* Web site (80 FR 41290).

2. Quality Measures for Performance Year 1 (CY 2016) and Subsequent Years

a. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550)

(1) Background

As stated in the proposed rule (80 FR 41278 through 41280), THA and TKA are commonly performed procedures for the Medicare population that improve quality of life. We indicated that between 2009 and 2012, there were 337,419 total hip arthroplasty (THA) procedures and 750,569 total knee arthroplasty (TKA) procedures for Medicare FFS patients 65 years and older,[57] that the post-operation complications of these procedures are high considering these are elective procedures, and recognized that complications are devastating to patients. We highlighted as an example, the rates for periprosthetic joint infection, which is a rare but devastating complication. We indicated reported rates of 2.3 percent for THA/TKA patients with rheumatoid arthritis after 1 year of follow-up,[58] and 1.6 percent in Medicare patients undergoing TKA after 2 years of follow up.[59] In the proposed rule (80 FR 41278), we also shared complication rates based on studies reporting on 90-day death rates following THA,[60] [61] reported rates for pulmonary embolism following TKA,[62] [63] [64] septicemia during an index admission,[65] and 90-days following discharge for primary TKA,[66] and rates for bleeding and hematoma following TKA.[67] [68] For combined THA and TKA procedures, we also noted in the proposed rule that these two procedures account for the largest payments for procedures under Medicare.[69] We shared our observation that while both hip and knee arthroplasty procedures improve the function and quality of life of patients with disabling arthritis, the volume and cost associated with these procedures are very high, and we believe it is important to assess the quality of care provided to Medicare beneficiaries who undergo one or both of these procedures.

In order to address these concerns and our reasons for proposing the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) measure, we shared historical information about this measure regarding its development, implementation in CMS programs, and its public display. Briefly, we indicated in the proposed rule (80 FR 41278) that the median hospital-level RSCR 2008 was 4.2 percent, with a range from 2.2 percent to 8.9 percent in hospitals and that we believe variation in complication rates suggests that there are important differences in the quality of care delivered across hospitals, and therefore room for quality improvement. In response to noted 2008 variation in complication rates, we developed, in 2010, the proposed measure of Hospital-Level RSCR Following Elective Primary THA and/or TKA, which attained National Quality Forum endorsement (NQF #1550) and recommendations from the NQF Measure Application Partnership (MAP) for use in the HIQR Program.[70] We also shared in the proposed rule that this measure has additionally been implemented in the HVBP program and that CMS has not submitted this measure to the NQF MAP for recommendations on use in the PAC settings since the measure was developed for the acute care hospital setting. Regarding public display of this measure, we indicated that this measure has been publicly reported on *Hospital*

[57] Suter L, Grady JL, Lin Z *et al.:* 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). 2013. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[58] Bongartz, T, Halligan CS, Osmon D, et al. Incidence and risk factors of prosthetic joint infection after total hip or knee replacement in patients with rheumatoid arthritis. Arthritis Rheum. 2008; 59(12): 1713–1720.

[59] Kurtz S, Ong K, Lau E, Bozic K, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. Clin Orthop Relat Res. 2010;468:5.

[60] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684. Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond, DS. Factors That Predict Short-term Complication Rates After Total Hip Arthroplasty. Clin Orthop Relat Res. Sep 2010;468(9):2363–2371.

[61] Soohoo NF, Farng E, Lieberman JR, Chambers L, Zingmond DS. Factors that predict short term complication rates after total hip arthroplasty. Clin Orthop Relat Res. Sep 2010; 468(9): 2363–2371.

[62] Mahomed NN, Barrett JA, Katz JN, *et al.* Rates and outcomes of primary and revision total hip replacement in the United States Medicare population. J Bone Joint Surg Am. Jan 2003;85–A(1):27–32.

[63] Khatod M, Inacio M, Paxton EW, *et al.* Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. Dec 2008;79(6):812–819.

[64] Solomon DH, Chibnik LB, Losina E, *et al.* Development of a preliminary index that predicts adverse events after total knee replacement. Arthritis & Rheumatism. 2006;54(5):1536–1542.

[65] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[66] Cram P, Vaughan-Sarrazin MS, Wolf B, Katz JN, Rosenthal GE. A comparison of total hip and knee replacement in specialty and general hospitals. J Bone Joint Surg Am. Aug 2007;89(8):1675–1684.

[67] Browne, JA, Cook C, Hofmann A, Bolognesi MP. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. 2010;17(2): 152–156.

[68] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1): 95–100.

[69] Bozic KJ, Rubash HE, Sculco TP, Berry DJ., An analysis of Medicare payment policy for total joint arthroplasty. J Arthroplasty. Sep 2008; 23(6 Suppl 1):133–138.

[70] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2012/02/MAP_Pre-Rulemaking_Report_Input_on_Measures_Under_Consideration_by_HHS_for_2012_Rulemaking.aspx* . Accessed on April 1 6, 2015, page 78.

*Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) since FY 2014 and in the HIQR Program since FY 2015 (FY 2015 IPPS/LTCH final rule, 79 FR 50062).

Finally, in the proposed rule we explained what the measure assesses, which is a hospital's risk standardized complication rate. We also specifically shared that the measure focuses on the rate of complications occurring 90 days after elective primary THA and TKA surgery. We explained that the 90-day period begins with the date of the index admission for a specific hospital, and that the index admission is the hospitalization to which the complications outcome is attributed. We also explained that either one or more of the following are considered complications in this measure: Acute myocardial infarction, pneumonia, or sepsis/septicemia within 7 days of admission; surgical site bleeding, pulmonary embolism or death within 30 days of admission; or mechanical complications, periprosthetic joint infection or wound infection within 90 days of admission. To highlight more recent data on THA/TKA procedure complications, we shared a comparison of the median hospital-level RSCRs for hospitals between April 1, 2011 and March 31, 2014 and noted a that there continues to be a performance gap (median RSCR of 3.1 percent with a range from 1.4 percent to 6.9 percent) indicating there is still room for quality improvement.[71]

(2) Data Sources

In the proposed rule (80 FR 41279), we proposed to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source to calculate the measure. We also explained that the index admission diagnoses and in-hospital comorbidities are assessed using Medicare Part A claims, and that additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 1 to 2 months prior to the index (initial) admission. Finally, in the proposed rule, we stated that enrollment and post-discharge mortality status are obtained from Medicare's enrollment database which contains beneficiary demographic, benefits/coverage, and vital status information.

(3) Cohort

In the proposed rule (80 FR 41279), we proposed that the cohort for the THA/TKA Complications measure (NQF #1550) would include Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We explained that THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively. We also proposed that the cohort would include all hospitals included in the model, but also noted the model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR Program. We noted this difference because the model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR Program acute care hospitals (for a detailed discussion on selection of hospitals for the model, see section III.A.4. of the proposed rule).

(4) Inclusion and Exclusion Criteria

We also proposed inclusion and exclusion criteria (80 FR 41279). We indicated that an index admission is the hospitalization to which the complication outcome is attributed. We also proposed that the measure include the following index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Enrolled in Part A and Part B Medicare for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ PHA procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

In the proposed rule, we indicated that the THA/TKA Complications measure (NQF #1550) would exclude the following admissions:

- Admissions for patients discharged against medical advice (AMA).
- Admissions for patients with more than two THA/TKA procedure codes during the index hospitalization.
- Consistent with the FY 2016 IPPS/LTCH proposed rule, admissions for patients without at least 90 days post-discharge enrollment in FFS Medicare; this exclusion is an update to the measure signaled in the HIQR Program section of the FY2016 IPPS/LTCH proposed rule (80 FR 24572 through 24574) to ensure that disproportionate Medicare FFS disenrollment does not bias the measure results.

We further explained in the proposed rule that once the exclusion criteria were applied, we randomly select one index admission for patients with multiple index admissions in a calendar year. Therefore, we exclude the other eligible index admissions in that year. Identification and use of a single index admission in a calendar year is done because this measure includes mortality as an outcome and the probability of death increases with each subsequent admission, preventing each episode of care from being mutually independent. Therefore only one index admission is selected to maintain measure integrity.

In the proposed rule, we also noted that THA/TKA Complications measure (NQF #1550) does not capture patients undergoing PHA procedures. We explained why we exclude PHA procedures, and this is primarily because PHA procedures are done for hip fractures and therefore are not elective procedures. We also shared that PHA procedures are typically performed on patients who are older, frailer, and have more comorbid conditions. We noted that although this exclusion is not fully harmonized with MS–DRG 469 and 470, which include PHA procedures, this measure still provides strong incentive for improving and maintaining care quality across joint replacement patients as hospitals typically develop protocols for lower extremity joint arthroplasty that will address perioperative and post-operative care for both total and PHA procedures. As previously cited in our discussion of the Episode Definition of the model (80 FR 41212 through 41219), the frequency of administrative claims data using ICD–9 codes for 2014 indicated that PHA (ICD–9 code: 81.52) accounted for 12 percent of the administrative claims, while Total Hip replacement (ICD–9 code: 81.51) and Total Knee replacement (ICD–9 code: 81.54) accounted for 87 percent of the administrative claims for 2014. We also

[71] Suter L, Zang W, Parzynski C, et al. 2015 Procedure-Specific Complication Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 4.0). 2015.

noted that the same surgeons and care teams frequently perform both procedures, and therefore quality improvement efforts initiated in response to the THA/TKA Complications measure (NQF #1550) are likely to benefit patients undergoing similar elective procedures, such as PHA and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

We note that we chose to align this measure with the risk-adjustment methodologies adopted for the HIQR Program and the HRRP in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act (FY 2013 IPPS/LTCH final rule 77 FR 53516 through 53518 and FY 2015 IPPS/LTCH final rule; 79 FR 50024, 50031, and 50202). We also indicated in the proposed rule (80 FR 41279) that the risk-adjustment takes into account the patient case-mix to assess hospital performance. The patient risk factors are defined using the Hierarchical Condition Categories (CC), which are clinically relevant diagnostic groups of ICD–9–CM codes.[72] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772783162*). We noted that the measure uses all Part A and B administrative claims ICD–9 codes for the year prior to and including the index admission. The Part A and B administrative claims ICD–9 codes are used to inform the risk prediction for each patient; diagnostic codes from PAC settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. Furthermore, we stated that use of the Part A and B data does not mean the measures are applicable to PAC settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. The measure would meet the requirement if it applied, because risk-adjustment adjusts for hospital patient mix, including age and comorbidities, to ensure that hospitals that care for a less healthy patient population are not penalized unfairly. In addition, we indicated that the measure methodology defines ''complications'' as acute myocardial infarction (AMI); pneumonia; sepsis/septicemia; pulmonary embolism; surgical site bleeding; death; wound infection; periprosthetic joint infection; and mechanical complication within 0 to 90-days post the index date of admission, depending on the complication. We explained that the decision to determine appropriate follow-up period of 0 to 90 days was based on our analysis of 90-day trends in complication rates using the 2008 Medicare FFS Part A Inpatient Data. We found that rates for mechanical complications are elevated until 90 days after the date of index admission. We also found that the rates for four other complications—death, surgical site bleeding, wound infection, and pulmonary embolism—are elevated for 30 days, and that rates for AMI, pneumonia, and sepsis/septicemia level off 7 days after the date of index admission.

(6) Calculating the Risk-Standardized Complication Rate (RSCR) and Performance Period

In the proposed rule (80 FR 41280), we shared that analogous to how we calculate hospital risk-standardized readmission rates with all readmission measures and risk-standardized mortality rates with the mortality measures used in CMS hospital quality programs, we also calculate the hospital RSCR by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw complication rate. As noted in the proposed rule, the THA/TKA Readmissions measure (NQF #1551) uses a 30-day window of follow-up, which is different from the 90-day window of follow-up used in the THA/TKA Complications measure (NQF #1550).

We also indicated that we would use a 3-year rolling performance period to be consistent with that used for the measure as it is implemented in the HIQR Program (FY 2015 IPPS/LTCH final rule, 79 FR 50208 and 50209). For performance year 1 of the model, we proposed that the performance period for the THA/TKA Complications measure (NQF #1550) would be April 2013 through March 2016. Section III.D.4. of this final rule summarizes performance periods for years 1 through 5 of the CJR model.

We sought public comment on this proposal to assess quality performance through implementation of the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measure.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters supported CMS's payment reform efforts and specifically focused on the need to improve complication rates through improvement of wound healing. They supported the use of the THA/TKA Complications measure (NQF #1550) as a means to change behavior and reduce complications.

*Response:* We thank these commenters for their support of payment reform and our efforts to reduce complications through the THA/TKA Complications measure (NQF #1550).

*Comment:* Commenters questioned the use of a 90-day episode timeframe for measuring patient outcomes following THA/TKA. One of the commenters specifically questioned the use of 2008 data to define the 90-day THA/TKA Complications measure (NQF #1550) timeframe, noting there may have been a significant shift in the occurrence of complications in the past 7 years.

*Response:* From a quality measure perspective, we note that the THA/TKA Complications measure (NQF #1550) uses different follow-up timeframes, up to 90 days, to assess different complications. We noted our rationale for the 90-day timeframe in the preamble of the proposed rule (80 FR 41217). Our measure development contractor consulted a Technical Expert Panel to review appropriate follow-up timeframes for each complication. Clinical experts agreed that the specified complications are more likely to be attributable to the index procedure if they occur within the specified timeframes. Additionally, we requested public comments during measure development, the rulemaking process, and regular measure maintenance during NQF and MAP review. We conduct annual and comprehensive reevaluation of the measure's methodology. We will take the commenter's suggestion to evaluate shifts in the occurrence of complications into consideration during the annual measure reevaluation process.

*Comment:* A commenter sought confirmation that CMS has quality improvement efforts that included the use of intermittent pneumatic

[72] Pope G, Ellis R, Ash A, et al., Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000;21(3):26.

compression devices (IPCD) to minimize medical and surgical complications during surgery and the postoperative period.

*Response:* We appreciate this inquiry regarding the inclusion of IPCD in CMS quality improvement efforts. We note that HIQR Program implemented two of The Joint Commission's venous thromboembolism measures that cover the use of IPCDs: 1) Venous thromboembolism prophylaxis measure 1 (VTE–1) (NQF #0371); and 2) Intensive Care Unit VTE Prophylaxis (VTE–2) (NQF #0372). We refer reviewers to FY 2016 IPPS/LTCH final rule (80 FR 49649) for discussion of use of these measures in the HIQR Program. These results are also available on *Hospital Compare* (available at: *https://www.medicare.gov/hospitalcompare/search.html*).

*Comment:* There were many comments requesting risk-adjustment of the payment methodology and/or the risk-adjustment at the measure level for socio-economic status or socio-demographic status. We noticed the terms socio-economic status and socio-demographic status were used interchangeably throughout many of the public comments. For clarity and simplicity, we will use socio-demographic status (SDS) to signify both socio-economic status and socio-demographic status. Some stakeholders indicated that the SDS of patients should be taken into account in the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). These stakeholders indicated that income factors such as percentage of dual eligible patients or Supplemental Security Income percentage, and family size or other post-discharge support measures should be risk adjusted. Some stakeholders shared their anecdotal data that demonstrated lower SDS was associated with poorer patient outcomes compared to other levels of SDS status.

*Response:* We continue to align our policy on SDS risk adjustment at the measure level across our quality and payment programs. Consistent with statements made in the FY 2016 IPPS/LTCH final rule (80 FR 49531 through 49532) and final rules related to PAC quality programs (IRF, 80 FR 47088; LTCH, 80 FR 49731; and SNF, 80 FR 46435), while we appreciate the importance of the role that SDS plays in the care of patients, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures. To date, we have found that hospitals that care for large proportions of patients of low sociodemographic status are capable of performing well on our measures (for example, we refer readers to the 2014 Chartbook pages 48–57, 70–73, and 78 at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*).

NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For two years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, ASPE is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs and the CJR model at such time as they are available.

*Comment:* A commenter expressed concern that the penalty for the quality threshold is biased against low-volume hospitals. The commenter stated that one or two readmissions or complications at a low-volume hospital would have a larger impact on the quality threshold, which would make it more difficult for to become eligible for incentive payments.

*Response:* We appreciate the commenter's concern, and note that we adopted a risk adjustment modeling methodology that takes into account volume. We acknowledge that smaller hospitals typically have less certain estimates because they have fewer cases for use in assessing quality. Our approach to modeling addresses the concern that the measures are biased against small hospitals due to random variation, and this challenge is inherent in outcome measurements. However, one advantage of the statistical model used for the measures is that it allows for the inclusion of small hospitals while characterizing the certainty of their estimates. The hierarchical logistic regression model that we use to calculate the risk-standardized measures allows the inclusion of hospitals with relatively few observations, but takes into account the uncertainty associated with sample size in estimating their risk-standardized outcome rates. The model takes into account the uncertainty in the estimate of outcome rates for low-volume hospitals by assuming that each hospital is a typically performing hospital. It weighs that assumption along with the outcomes for the particular hospital in calculating the outcome rate. Therefore, the estimated outcome rates for smaller hospitals will likely be closer to the national average because the limited number of eligible cases in the hospital indicated relatively little about that hospital's true outcome rate.

*Comment:* A commenter recommended that CMS incorporate pre-operative global physical function, BMI, smoking status, musculoskeletal comorbidities and Charlson comorbidity index into the existing THA/TKA Complications (NQF #1550) and Readmissions (NQF #1551) measures' risk models.

*Response:* In addition to risk adjusting for multiple comorbid medical conditions, these measures currently risk adjust for ICD–9–CM codes 278.01 Morbid Obesity, 755.63 Skeletal Deformities and 716.15/716.16 Post-Traumatic Osteoarthritis, as well as a large number of other musculoskeletal conditions. We undertake a comprehensive measure reevaluation of our existing publicly reported outcome measures each year. Currently, these measures utilize administrative claims data for risk adjustment. When additional risk factor data sources become widely available, we will take these recommendations under advisement for incorporation into future iterations of these measures through rulemaking.

*Final Decision:* After consideration of the public comments we received, we are finalizing and adopting the THA/TKA Complications measure (NQF #1550) as proposed. Regarding the requests for socio-demographic risk-adjustment at the measure level, we will not be risk-adjusting the CJR model measures for socio-demographic variables at this time. As previously noted, we await further information from ASPE's research and recommendations. Finally, we are codifying adoption of the Hospital-Level

Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) in § 510.400(a)(1).

b. Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551)

(1) Background

In the proposed rule (80 FR 41280), we stated that the objective of CMS's Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) (as referred to as THA/TKA Readmissions measure (NQF #1551)) measure is to assess readmission from any cause within 30 days of discharge from the hospital following elective primary THA and TKA. As previously stated, outcome measures such as complications and readmissions are the priority areas for the HIQR Program, and elective primary THA and TKA are commonly performed procedures that improve quality of life. We also stated our belief that THA and TKA readmissions are disruptive to patients' quality of life, costly to the Medicare program, and that data support that readmission rates can be improved through better care coordination and other provider actions.[73] Furthermore, we stated our belief that there is an opportunity for hospitals to improve quality of life for the patient. We shared in the proposed rule that from July 1, 2011 to June 30, 2014, Medicare FFS claims data indicate that 30-day hospital-level risk-standardized readmission rates ranged from 2.6 percent to 8.5 percent among hospitals with a median rate of 4.8 percent with a mean risk-standardized readmission rate of 4.9 percent.[74] This range in variation suggests there are important differences in the quality of care received across hospitals, and that there is room for improvement. We shared our belief that a measure that addresses readmission rates following THA and TKA procedures not only provides an opportunity to provide targets for efforts to improve the quality of care and reduction in costs for patients undergoing these elective procedures, but also increases transparency for consumers and provides patients with information that could guide their choices. We indicated our belief that a risk-adjusted readmission outcome measure can provide a critical perspective on the provision of care, and supports improvements in care for the Medicare patient population following THA/TKA hospitalization. In the proposed rule, we provided historical background on the THA/TKA Readmissions measure (NQF #1551), indicating that the measure has wide stakeholder support, with NQF endorsement in January 2012, and recommendations by the NQF MAP for use in the HIQR Program (2012 Pre-Rulemaking report [19]), and in the HRRP (2013 Pre-Rulemaking report).[75] Finally, we shared that the THA/TKA Readmissions Measure (NQF #1551) has been publicly reported since FY 2014 (79 FR 50062), and was implemented in both the HIQR Program (77 FR 53519 through 53521) and HRRP (78 FR 50663 and 50664).

(2) Data Sources

In the proposed rule (80 FR 41280), we proposed to use Medicare Part A and Part B FFS claims submitted by the participant hospital as the data source for calculation of the THA/TKA Readmissions measure (NQF #1551). We stated that index admission diagnoses and in-hospital comorbidity data are assessed using Medicare Part A claims and that additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. We shared that enrollment status is obtained from Medicare's enrollment database which contains beneficiary demographic, benefit/coverage, and vital status information.

(3) Cohort

In the proposed rule (80 FR 41281), we indicated that THA/TKA Readmissions measure (NQF #1551) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We explained that the THA and TKA procedures eligible for inclusion are defined using ICD–9–CM codes 81.51 and 81.54, respectively, and proposed that the cohort will include all hospitals included in the model, but the model cohort may differ slightly from the hospital cohort that is currently captured in the measures through the HIQR Program. That is, the model cohort is a randomly selected group of acute care hospitals and therefore may not include all of the HIQR Program acute care hospitals (for a detailed discussion on selection of hospitals for the model see section III.A. of the proposed rule).

(4) Inclusion and Exclusion Criteria

In the proposed rule (80 FR 41281), we proposed that an index admission is the anchor hospitalization to which the readmission outcome is attributed. The measure includes the following index admissions for patients:

- Enrolled in Medicare FFS.
- Aged 65 or over.
- Discharged from non-federal acute care hospitals alive.
- Enrolled in Medicare Part A and Part B for the 12 months prior to the date of index admission and during the index admission.
- Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

++ Femur, hip, or pelvic fractures coded in principal or secondary discharge diagnosis fields of the index admission.

++ PHA procedures with a concurrent THA/TKA.

++ Revision procedures with a concurrent THA/TKA.

++ Resurfacing procedures with a concurrent THA/TKA.

++ Mechanical complication coded in the principal discharge diagnosis field.

++ Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

++ Removal of implanted devices/prostheses.

++ Transfer from another acute care facility for the THA/TKA.

- This measure excludes index admissions for patients—

++ Without at least 30 days post-discharge enrollment in FFS Medicare;

++ Discharged against medical advice (AMA);

++ Admitted for the index procedure and subsequently transferred to another acute care facility; and

++ With more than two THA/TKA procedure codes during the index hospitalization.

[73] Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: A systematic meta-review. *BMC Health Services Research*. 2007;7:47.

[74] Suter L, Desai N, Zang W, *et al.* 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Risk-Standardized Readmission Measure (Version 4.0), Isolated Coronary Artery Bypass Graft (CABG) Surgery—Version 2.0. 2015; *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[75] National Quality Forum. MAP Final Reports. Available at: *http://www.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-__-_February_2013.aspx.* Accessed on April 16, 2015, page 143.

Finally, we also indicated that for the purpose of this measure, admissions within 30 days of discharge from an index admission are not eligible to also be index admissions. Thus, no hospitalization will be counted as both a readmission and an index admission in this measure.

In the proposed rule, we also stated that this measure does not capture patients undergoing PHA procedures, as partial hip arthroplasties are primarily done for hip fractures and are typically performed on patients who are older, frailer, and have more comorbid conditions. We also shared that although this exclusion is not fully harmonized with MS–DRG 469 and 470, which include PHA procedures, this measure would still provide strong incentive for improving and maintaining care quality across joint replacement patients. We shared our belief that the THA/TKA Readmissions measure (NQF #1551) provides strong incentive for quality improvement because hospitals typically develop protocols for lower extremity joint arthroplasty that will address perioperative and post-operative care for both total and partial hip arthroplasties, and the same surgeons and care teams frequently perform both procedures. Therefore, quality improvement efforts initiated in response to the THA/TKA Readmissions measure (NQF #1551) are likely to benefit patients undergoing similar elective procedures, such as PHA and revision THA/TKA procedures, and possibly even non-elective THA/TKA procedures, such as fracture-related THA.

(5) Risk-Adjustment

In the proposed rule (80 FR 41281), we noted that we chose to align this measure with the risk-adjustment methodologies adopted for Readmissions measure (NQF #1551) under the HIQR Program in accordance with section 1886(b)(3)(B)(viii)(VIII) of the Act, as finalized in FY 2013 IPPS/LTCH PPS final rule (77 FR 53519 through 53521). We also noted that the measure risk-adjustment takes into account patient age and comorbidities to allow a fair assessment of hospital performance. Further, we noted that the measure defines the patient risk factors for readmission using diagnosis codes collected from all patient claims 1 year prior to patient index hospitalization for THA and TKA. We also indicated that as previously noted for the THA/TKA Complications measure (NQF #1550), Parts A and B administrative claims ICD–9 codes are used to inform the risk prediction for each patient; diagnostic codes from PAC settings are included in the measure, but this information is only used to identify a hospital's patient case mix in order to adequately adjust for differences in case mix across hospitals. We stated that use of the Part A and B data does not mean the measures are applicable to PAC settings, only that they use comprehensive data to predict the risk of the outcome and adjust for hospital patient case mix. We noted that the patient diagnosis codes are grouped using Hierarchical Condition Categories (CCs), which are clinically relevant diagnostic groups of ICD–9–CM codes.[76] The CCs used in the risk adjustment model for this measure, are provided on the CMS QualityNet Web site (*https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1219069856694*). We concluded with the summary that age and comorbidities present at the time of admission are adjusted for differences in hospital case mix (patient risk factors), and that the measure uses the hierarchical logistic regression model (HLM) statistical methodology for risk adjustment.

(6) Calculating the Risk-Standardized Readmission Rate and Performance Period

In the proposed rule (80 FR 41281), we proposed to calculate hospital risk-standardized readmission rates consistent with the methodology used to risk standardize all readmission measures and mortality measures used in CMS hospital quality programs. We stated that using HLM, we calculate the hospital-level elective primary THA/TKA risk-standardized readmission rate by producing a ratio of the number of ''predicted'' readmissions (that is, the adjusted number of readmissions at a specific hospital) to the number of ''expected'' readmissions (that is, the number of readmissions if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national raw readmission rate. We also indicated that use of the 3-year rolling performance period would be consistent with that used for the HIQR Program (FY 2015 IPPS/LTCH final rule 79 FR 50208 and 50209). For performance year one of the model, we proposed that the performance period for the THA/TKA Readmissions measure (NQF #1551) would be July 2013 through June 2016. As noted in the proposed rule for the section on the THA/TKA Complications measure (NQF #1550), there is a 90-day window of follow-up, which is different from the THA/TKA Readmissions measure (NQF #1551). Section III.D.4. of this final rule summarizes performance periods for years 1 through 5 of the model years.

We invited public comments on this proposal to include Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) or both in the model to assess quality performance. We also invited public comment on inclusion of other potential quality measures in the model.

The following is a summary of the comments received and our responses.

*Comment:* A commenter noted the variation in 30-day readmission rates (80 FR 41280) and stated that the variation may not only be due to differences in quality of care, but also patient age, comorbid conditions, and geographic location.

*Response:* We appreciate the commenter's input. We note that the THA/TKA Readmissions measure (NQF #1551) risk adjusts for patients' risk factors, including age and comorbid conditions, thereby taking into account case mix differences across providers. Adjusting for case mix is an important aspect for measuring a RSRR that accurately reflects factors that can confound an outcome rate when not adequately adjusted. The goal of risk adjustment for this measure is to account for patient and procedure characteristics and comorbid conditions that are clinically relevant and have strong relationships with readmission, while illuminating important quality differences between hospitals. The measure does not adjust for geographic location because location is associated with the different care patterns than those the measure seeks to illuminate.

*Comment:* A commenter sought clarification regarding the readmission exclusions described in section III.D.2.b.(4). of this final rule for the CJR model episode definition. The commenter stated that they were unclear on the rationale that CMS used to determine that all medical MS–DRGs for readmission be included in the episodes as related services with the exception of oncology and trauma medical MS–DRGs.

*Response:* We note that there are two separate discussions about readmissions in the CJR model proposed rule found in sections III.B. and III.D. of this final rule, in which the episode definition and the THA/TKA Readmissions measure (NQF #1551) are, respectively,

[76] Pope G, Ellis R, Ash A, *et al.,* Principal Inpatient Diagnostic Cost Group Models for Medicare Risk Adjustment. Health Care Financing Review. 2000; 21(3):26.

discussed in detail. In section III.B. of the proposed rule, the discussion of the Episode Definition and its related services describes the services included and excluded in an episode of care for this model (80 FR 41213 through 41215). We note that section III.B.2.b. of this final rule is specific to the discussion of readmission exclusions related to the oncology and trauma MS–DRGs. In section III.D. of the proposed rule, we detailed the measure specifications of the THA/TKA Readmissions measure (NQF #1551). We note, from the measure perspective, two important aspects of what is included or excluded from the measure: (1) The THA/TKA Readmissions measure (NQF #1551) does count all unplanned readmissions, including those related to trauma since a trauma patient is not considered a planned readmission; and (2) the THA/TKA Readmissions measure (NQF #1551) is designed to capture readmissions that arise from acute clinical events requiring urgent readmission within 30 days of discharge. These two important aspects of the measure exist because we use all-cause *unplanned* readmission for several reasons. First, from the patient perspective, readmission for any cause is a key concern. Second, limiting the measure to THA/TKA-related readmissions may make it susceptible to gaming. Moreover, it is often hard to exclude quality issues and accountability based on the documented cause of readmission. For example, a THA/TKA patient who develops a hospital-acquired infection may ultimately be readmitted for sepsis. It would be inappropriate to treat this readmission as unrelated to the care the patient received during their admission for a THA/TKA procedure. Finally, while the measure does not presume that each readmission is preventable, appropriate interventions have generally shown reductions in all-cause readmission. Examples of appropriate interventions include, but are not limited to, adherence to clinical guidelines to prevent hospitals-acquired infections and surgical complications, as well as coordination of follow-up care at the time of discharge, patient education regarding the dosing and purpose of their medications, and ensuring appropriate follow-up. Planned readmissions, which are generally not a signal of quality of care, are not counted in the measure outcome. The measure uses CMS's Planned Readmission Algorithm Version 3.0—THA/TKA Population to define planned readmissions for exclusion from the measure outcome. Therefore, from a measure perspective, oncology patients who are readmitted to receive maintenance chemotherapy are not counted as being readmitted by the algorithm and are therefore not considered readmissions in the 30-day all cause THA/TKA RSRR measure. As previously stated, a trauma patient is not considered a planned readmission and will be counted in the measure outcome for the reasons stated previously.

*Comment:* We received a comment from the MedPAC with which many other commenters cited and with which they expressed agreement. The commenters encouraged CMS not to use the THA/TKA Readmissions measure (NQF #1551) in more than one payment program. A few of the commenters also recommended to not use the HCAHPS Survey measure (NQF #0166) in two payment programs. Some commenters made suggestions to remove the THA/TKA Readmissions measure (NQF #1551) from the Hospital Readmission Reduction Program or the HCAHPS Survey measure (NQF #0166) from the Hospital Value-Based Purchasing program if these measures were implemented in the CJR model.

*Response:* We acknowledge the request of many commenters to remove the THA/TKA Readmissions measure (NQF #1551) from the CJR model due to the incentives, already in place by the HRRP, for hospitals to lower excess readmission rates. Upon further consideration of the quality measure set proposed for use in the CJR model, and to be responsive to stakeholder concerns, we have decided not to finalize inclusion of the THA/TKA Readmissions measure (NQF #1551) for the CJR model. We believe that finalizing the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) effectively supports the intent of the CJR model to decrease cost while ensuring that quality of care for LEJR episodes is maintained or improved. We note that the THA/TKA Complications measure (NQF #1550) focuses on primary elective THA and TKA procedure cases that will help to provide necessary information about quality performance for patients and providers considering an elective procedure and that the HCAHPS Survey measure (NQF #0166) will help provide important information about patient experience during hospitalizations. We still consider THA/TKA Readmissions measure rates to be an important metric for providing information about hospital performance, and while we did not propose any changes to the HIQR Program or HRRP, we note that we will continue to use the THA/TKA Readmissions measure (NQF #1551) in the HIQR Program and HRRP for public reporting and payment purposes. We note that there is still room for hospitals to improve on this measure based on the previously discussed distribution of hospital measure results in the proposed rule (80 FR 41280 section III.D.2.b.(1)).

With respect to some commenters' concerns regarding the overlap of the measures chosen for the CJR model with measures used in other Medicare payment programs, we acknowledge that there is some overlap in quality measures between the CJR model and the HVBP program and HRRP. While we are aware that commenters object to the possibility of scoring hospitals on certain measures under more than one program or model, we note that the measures we are finalizing for the CJR model cover topics of critical importance to quality improvement for THA/TKA patients, namely, post-surgical complications and patient experience during hospitalizations, as well as the CJR model's broader goals of improving care coordination while lowering costs. In light of the CJR model's goals, we believe it is appropriate to provide strong incentives for hospitals to improve these aspects of patient care quality by using the finalized measures under more than one program or model.

We also note that the CJR model is separate and distinct from the HVBP program and HRRP, which have different purposes and policy goals. The CJR model aims to improve the care experience of Medicare patients who receive joint replacements by focusing on coordinated, patient-centered care while also lowering costs. On the other hand, the HVBP Program is an incentive program that redistributes a portion of the Medicare payments made to hospitals based on their performance on various measures. HRRP is an incentive program that links Medicare payments to hospitals based on their performance on readmission measures compared to the national rate for excess readmissions. Therefore, although the measures finalized for the CJR model exist in more than one program, the measures are used and calculated for distinct purposes. Accordingly, we believe that the critical importance of these measures to THA/TKA patient safety and experience warrant their inclusion in more than one program. We will monitor the use of the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) in the CJR model, including any unintended consequences of having a measure in more than one program, and

will revise the measure set in one or more programs if needed through rulemaking. We will not be finalizing the THA/TKA Readmissions measure (NQF #*1551) in the CJR model.*

*Final Decision:* After consideration of the many public comments received on the proposal to adopt the THA/TKA Readmissions measures (NQF #1551) for the CJR model, we are not finalizing the THA/TKA Readmissions measure (NQF #1551) for the CJR model for the reasons discussed in this section.

c. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey (NQF #0166)

(1) Background

In the proposed rule (80 FR 41282), we proposed to adopt the HCAHPS Survey (NQF #0166) measure. We indicated that the HCAHPS Survey measure (NQF #0166) is a CMS survey and a national, standardized, publicly reported survey of patients' experience of hospital care, and that CMS is the measure steward. We also shared that the HCAHPS Survey measure is endorsed by the NQF (#0166), and stated that the HCAHPS survey (NQF #0166), also known as CAHPS® Hospital Survey, is a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. We explained how the HCAHPS survey asks recently discharged patients 32 questions about aspects of their hospital experience that they are uniquely suited to address, where the core of the survey contains 21 items that ask ''how often'' or whether patients experienced a critical aspect of hospital care. We also indicated that the survey also includes four items to direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports (see 77 FR 53513 through 53515).

In the proposed rule, we noted that eleven HCAHPS measures (seven composite measures, two individual items and two global items) are currently publicly reported on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) for each hospital participating in the HIQR Program (see 79 FR 50259.) Each of the seven currently reported composite measures is constructed from two or three survey questions. The seven composites summarize the following:

- How well doctors communicate with patients.
- How well nurses communicate with patients.
- How responsive hospital staff are to patients' needs.
- How well hospital staff helps patients manage pain.
- How well the staff communicates with patients about medicines.
- Whether key information is provided at discharge.
- How well the patient was prepared for the transition to post-hospital care.

Lastly, the two individual items address the cleanliness and quietness of patients' rooms, while the two global items report patients' overall rating of the hospital, and whether they would recommend the hospital to family and friends. We proposed to adopt a measure in the model that uses HCAHPS survey data to assess quality performance and capture patient experience of care.

(2) Data Sources

In the proposed rule (80 FR 41282), we explained that the HCAHPS survey is administered to a random sample of adult inpatients between 48 hours and 6 weeks after discharge. As discussed in section III.D.5. of the proposed rule, we noted the following: (1) The HCAHPS survey data is collected on inpatient experience, is not limited to Medicare beneficiaries, and does not distinguish between types of Medicare beneficiaries; (2) patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; the survey is not restricted to Medicare beneficiaries; (3) hospitals may use an approved survey vendor, or collect their own HCAHPS data (if approved by CMS to do so) (for a detailed discussion, see 79 FR 50259); and (4) to accommodate hospitals, the HCAHPS survey can be implemented using one of the following four different survey modes:

- Mail.
- Telephone.
- Mail with telephone follow-up.
- Active Interactive Voice Recognition (IVR).

We also noted that regardless of the mode used, hospitals are required to make multiple attempts to contact patients, and that hospitals may use the HCAHPS survey alone, or include additional questions after the 21 core items discussed previously. We also indicated the timeframes (that is, surveying must begin from 48 hours to 42 days following hospital discharge) and number of patients that hospitals must survey patients monthly throughout the year (80 FR 41282 in section III.D.2.c.(2) and III.D.2.c.(3) of the proposed rule), and that hospitals participating in the HIQR Program must target at least 300 completed surveys over 4 calendar quarters in order to attain the reliability criterion CMS has set for publicly reported HCAHPS scores (see 79 FR 50259). Finally we noted that the survey itself and the protocols for sampling, data collection, coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines manual, available on the HCAHPS Web site located at: *http://www.hcahpsonline.org.* (The HCAHPS survey is available in several languages, and all official translations of the HCAHPS survey instrument are available in the current HCAHPS Quality Assurance Guidelines at *http://www.hcahpsonline.org/qaguidelines.aspx*.)

(3) Cohort

In the proposed rule (80 FR 41282), we noted that hospitals, or their survey vendors, submit HCAHPS data in calendar quarters (3 months). Consistent with other quality reporting programs, we proposed that HCAHPS scores would be publicly reported on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) based on 4 consecutive quarters of data. For each public reporting, the oldest quarter of data is rolled off, and the newest quarter is rolled on (see 79 FR 50259).

(4) Inclusion and Exclusion Criteria

In the proposed rule (80 FR 41282), we stated that the HCAHPS survey is broadly intended for patients of all payer types who meet the following criteria:

- Eighteen years or older at the time of admission.
- Admission includes at least one overnight stay in the hospital.
- Non-psychiatric MS–DRG/principal diagnosis at discharge.
- Alive at the time of discharge.

There are a few categories of otherwise eligible patients who are excluded from the sample frame as follows:

- ''No-Publicity'' patients—Patients who request that they not be contacted.
- Court/Law enforcement patients (that is, prisoners); patients residing in halfway houses are included.
- Patients with a foreign home address (U.S. territories—Virgin Islands, Puerto Rico, Guam, American Samoa, and Northern Mariana Islands are not considered foreign addresses and are not excluded).
- Patients discharged to hospice care (Hospice-home or Hospice-medical facility).
- Patients who are excluded because of state regulations.
- Patients discharged to nursing homes and SNFs.

We also indicted that the HCAHPS survey is intended for short-term, acute care hospitals. Both IPPS and CAHs

participate in the survey; specialty hospitals, psychiatric hospitals and children's hospitals do not.

(5) Case-Mix-Adjustment

In the proposed rule (80 FR 41282 through 41283), we stated that to ensure that HCAHPS scores allow fair and accurate comparisons among hospitals, CMS adjusts for factors that are not directly related to hospital performance but which affect how patients answer survey items. This includes the mode of survey administration and characteristics of patients that are out of a hospital's control. Patient-mix adjustments (also known as case-mix adjustment) control for patient characteristics that affect ratings and that are differentially distributed across hospitals. Most of the patient-mix items are included in the ''About You'' section of the survey, while others are taken from hospital administrative records. Based on the HCAHPS mode experiment,[77] and consistent with previous studies of patient-mix adjustment in HCAHPS and in previous hospital patient surveys, we employ the following variables in the patient-mix adjustment model:

- Self-reported general health status (specified as a linear variable).
- Education (specified as a linear variable).
- Type of service (medical, surgical, or maternity care).
- Age (specified as a categorical variable).
- Admission through emergency room (discontinued in 2010).
- Lag time between discharge and survey completion.
- Age by service line interaction.
- Language other than English spoken at home.

Finally, we indicated that once the data are adjusted for patient-mix, there is a fixed adjustment for the mode of survey administration (mail, telephone, mail with telephone follow-up, and active Interactive Voice Response) and information on patient-mix adjustment (risk adjustment) and survey mode adjustment of HCAHPS scores can be found at *http://www.hcahpsonline.org/modeadjustment.aspx*.

(6) HCAHPS Scoring

In the proposed rule (80 FR 41283), we outlined the methodology used to assess hospitals in the HIQR Program as reasonable for use in the model since this is a survey that many hospitals and patients are familiar with. In determining HCAHPS performance, we proposed to utilize the HLMR score because the HLMR summarizes performance across the 11 publicly reported HCAHPS measures for IPPS hospitals with 100 or more completed HCAHPS surveys in a 4-quarter period. We stated that the HLMR is calculated by taking the average of the linear mean scores (LMS) for each of the 11 publicly reported HCAHPS measures. We noted that the LMS, which was created for the calculation of HCAHPS Star Ratings, summarizes all survey responses for each HCAHPS measure; a detailed description of LMS can be found in HCAHPS Star Rating Technical Notes, at *http://www.hcahpsonline.org/StarRatings.aspx*.

We proposed that hospitals participating in the model also have at least 100 completed HCAHPS surveys over a given 4-quarter period to be evaluated on HCAHPS for the model.

We noted in the proposed rule that responses to the survey items used in each of the 11 HCAHPS measures described previously are combined and converted to a 0 to 100 linear-scaled score (LMS) as follows:

- ''Never'' = 0; ''Sometimes'' = 33⅓; ''Usually'' = 66⅔; and ''Always'' = 100 (For HCAHPS Survey items 1–9, 11, 13–14, and 16–17).
- ''No'' = 0; and ''Yes'' = 100 (For items 19 and 20).
- Overall Rating ''0'' = 0; Overall Rating ''1'' = 10; Overall Rating ''2'' = 20; . . . ; Overall Rating ''10'' = 100 (For item 21).
- ''Definitely No'' = 0; ''Probably No'' = 33⅓; ''Probably Yes'' = 66⅔; and ''Definitely Yes'' = 100 (For item 22).
- ''Strongly Disagree'' = 0; ''Disagree'' = 33⅓; ''Agree'' = 66⅔; and ''Strongly Agree'' = 100 (For items 23, 24, and 25).

The 0 to 100 linear-scaled HCAHPS scores are then adjusted for patient mix, survey mode, and quarterly weighting, see *http://www.hcahpsonline.org/files/HCAHPS_Stars_Tech_Notes_Apr2015.pdf*.

The HLMR summarizes performance across the 11 HCAHPS measures by taking an average of each of the LMS of the 11 HCAHPS measures, using a weight of 1.0 for each of the 7 HCAHPS composite measures, and a weight of 0.5 for each of the single item measures (Cleanliness, Quietness, Overall Hospital Rating and Recommend the Hospital). The HLMR is calculated to the second decimal place. Once the HLMR score is determined for a participant hospital, the hospital's percentile of performance can be determined based on the national distribution of hospital performance on the score.

(7) Performance Period

In the proposed rule (80 FR 41283), we proposed to be consistent with the HIQR Program, which uses four quarters of data (79 FR 50259). For the model, we proposed to use the most recently available HCAHPS 4-quarter roll-up to calculate the HLMR score for the initial year of the model. The performance period would assess data on patients discharged from July 1, 2015 through June 30, 2016 for the first year of the model. Section III.D.4. of this final rule summarizes performance periods for years 1 through 5 of the model years.

We invited public comments on this proposal to include HCAHPS Survey measure (NQF #0166) in the model to assess quality performance and capture patient experience of care.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters supported the inclusion of the HCAHPS Survey measure in the model and strongly recommended increasing the relative weighting of the HCAHPS Survey measure (NQF #0166) in the model. Commenters also cited the fact that the proposed HCAHPS Survey measure (NQF #0166) assesses both access to care and pain management. By contrast, many commenters said that the proposed HCAHPS Survey measure (NQF #0166) should not be included in the model because it does not capture the patient experience of care during the full 90-day episode.

*Response:* We thank the commenters for these observations and agree with the commenters supporting inclusion of the measure, as we believe it represents an important patient experience measure. We acknowledge that this survey is restricted to the inpatient population by capturing inpatients' experience of care at acute care hospitals. While we do not have an outpatient experience of care survey, we note that the acute care hospitals are the unit of analysis for the model from a measure perspective. Based on the currently available hospital-level patient experience measures, the HCAHPS Survey measure (NQF #0166) is the best available measure for capturing, assessing and comparing the inpatient experience of joint replacement patients at the hospital-level. Regarding the suggestion to increase the weighting of the HCAHPS Survey measure (NQF #0166) in the CJR model we refer readers to section III.C.5.b.(5)(c)(iii) in this final rule for detailed discussion of the relative weighting of this measure in reconciliation payment.

[77] The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' M.N. Elliott, A.M. Zaslavsky, E. Goldstein, W. Lehrman, K. Hambarsoomian, M.K. Beckett and L. Giordano. *Health Services Research,* 44(2): 501–518. 2009.

*Comment:* Many commenters stated that the HCAHPS Survey measure (NQF #0166) is inappropriate because it will capture a wide range of hospital inpatients along with hip and knee replacement surgery inpatients. CMS, they stated, should collect HCAHPS data on only patients who had undergone an elective THA/TKA, or had procedures captured by MS–DRG 469 and 470 who were involved in the CJR model and compensate hospitals for any additional costs incurred in this effort. A commenter stated that participating hospitals with a ''center of excellence'' program for total joint replacement patients may have in that dedicated unit excellent patient satisfaction scores, but other inpatient units may have less satisfied patients. Thus, HCAHPS scores derived from patients in the joint replacement unit would be undermined by combination at the hospital level with lower scores from other units. Another commenter stated essentially the opposite: That better patient experience of care in other hospital units would mask poorer performance in the joint replacement unit.

*Response:* We appreciate the concerns from the commenters about the broad patient population covered by this measure. Although the HCAHPS Survey encompasses a broader range of patients than does the model episode definition, we are not aware of evidence that such patients' experience of care differs markedly from those of the larger group of eligible patients after patient-mix adjustment for service line (surgery) and age have been applied. From a survey implementation standpoint, it is not feasible to target only Medicare beneficiaries who had hip or knee replacement surgery, or to calculate the HCAHPS Linear Mean Roll-up score on the basis of only those hip or knee replacement surgical patients. In addition to complicating the administration of the survey, the number of completed surveys from such a narrow set of patients would be, for many hospitals, too small to support reliable measurement or comparison. The inclusion of the HCAHPS Survey measure (NQF #0166) as currently implemented and the HLMR derived from it in the CJR model will present participating hospitals with a further incentive to improve experience of care for all patients.

We are finalizing our proposal to employ the HCAHPS Survey measure (NQF #0166) as currently implemented. HCAHPS, which was launched in 2006 and has been continuously administered ever since, is familiar to over 4,000 hospitals. Modifications to the standardized implementation protocols would be disruptive to the other programs that employ HCAHPS data, which include the HIQR Program and Hospital Value-Based Purchasing program.

*Comment:* Some commenters had questions about the HCAHPS Linear Mean Roll-up score proposed as the patient experience of care measure in the model, specifically regarding how it was calculated.

*Response:* We note that the HLMR summarizes in one statistic all survey responses to all 11 HCAHPS measures from all eligible patients discharged in a four-quarter period. As such, it is an efficient and complete summary of hospital patients' experience of care. The HLMR is created in the production of the HCAHPS Summary Star Ratings now displayed on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) and is derived directly from the linear mean scores of the 11 publicly reported HCAHPS measures. Information on the calculation of the HCAHPS linear mean scores can be found in the HCAHPS Star Rating Technical Notes on the HCAHPS On-Line Web site, *http://www.hcahpsonline.org/StarRatings.aspx*. The HLMR summarizes performance across the 11 HCAHPS measures by taking an average of each of the linear mean scores of the 11 HCAHPS measures, using a weight of 1.0 for each of the 7 HCAHPS composite measures, and a weight of 0.5 for each of the single-item measures (Cleanliness, Quietness, Overall Hospital Rating and Recommend the Hospital). The HLMR is calculated to the second decimal place (x.xx) and can range from 0.00 to 100.00.

*Comment:* Some commenters suggested that the HCAHPS Survey be modified to encompass patients discharged to nursing homes and SNFs before being used in the model.

*Response:* Patients discharged to nursing homes and SNFs are excluded from HCAHPS survey administration because of the difficulty contacting such patients and consistently surveying them in a timely manner. We are not aware of evidence that patients discharged to a nursing home or SNF have different experience of care than other inpatients in the hospital.

*Comment:* Some commenters stated that the HCAHPS Survey was arbitrarily biased against certain categories of hospitals such as urban hospitals, major teaching hospitals, safety-net hospitals, hospitals that receive a high proportion of their inpatients through the emergency department, and hospitals that serve a disproportionate share of uninsured, Medicaid, or Medicare dual-eligible patients.

*Response:* We have not seen evidence that the HCAHPS Survey is biased against any particular category of hospital. Both rural and urban hospitals and teaching and non-teaching hospitals have been found to perform well on the HCAHPS survey.[78] Currently, major teaching hospitals' performance on HCAHPS measures are sometimes lower, sometimes the same, and sometimes higher than that of minor teaching hospitals and non-teaching hospitals (available at: *http://www.hcahpsonline.org/SummaryAnalyses.aspx*). The hospital characteristic definitions are derived from a survey of hospitals conducted by the American Hospital Association (AHA) in 2012 and published in the *AHA Guide 2014 Edition.*

*Comment:* A commenter stated that the HCAHPS Survey would not be informative because of its low response rate.

*Response:* We do not believe that the response rate of the HCAHPS Survey degrades its ability to fairly capture patient experience of care. The national response rate for the HCAHPS Survey is currently 31 percent. The patient-mix adjustment that is applied to HCAHPS results prior to public reporting adequately addresses the non-response bias that would otherwise exist.[79] Recent meta-analyses suggest that non-response bias is less related to response rate per se than to the use of rigorous and standardized survey protocols.[80] [81]

*Comment:* Many commenters suggested that CMS replace the HCAHPS Survey with a patient experience of care measure targeted at only surgical patients, such as the CAHPS Surgical Care Survey, or only those patients eligible for the CJR model. A commenter stated that, while it would be inappropriate to use the CAHPS Surgical Care Survey as a pay-for-reporting or pay-for-performance tool because CMS had not tested this survey for national implementation, the

[78] Lehrman WG, Elliott MN, Goldstein E, Beckett MK, Klein DJ, Giordano LA. Characteristics of Hospitals Demonstrating Superior Performance in Patient Experience and Clinical Process Measures of Care. *Medical Care Research and Review,* 67(1): 38–55. 2010.

[79] Elliott MN, Zaslavsky AM, Goldstein E, Lehrman WG, Hambarsoomian K, Beckett MK, Giordano LA. The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores. *Health Services Research,* 44(2): 501–518. 2009.79.

[80] Groves RM. Nonresponse rates and nonresponse bias in household surveys. Public Opin Q. 2006; 70:646–675.

[81] Groves RM, Peytcheva E. ''The impact of nonresponse rates on nonresponse bias: a meta-analysis''. Public Opin Q. 2008; 72:167–189.

CAHPS Surgical Care Survey could be used for model evaluation purposes in the context of the CJR model's bundled payment approach. Many commenters suggested that CMS create a new survey instrument specifically for the CJR model that would capture the 90-day episode of care and combine patient experiences of care across all the providers that a patient encountered during that period.

*Response:* The CAHPS Surgical Care Survey is focused on the physician who performed inpatient or outpatient surgery, not the hospital, and encompasses a range of surgical patients, not just those included in the CJR model. We do not believe the CAHPS Surgical Care Survey measure is feasible or appropriate to adopt for the CJR model.

While a patient experience survey customized for only LEJR patients might have a tighter focus, developing and implementing such a measure would require significant resources and take a number of years. Given the relatively small number of patients at a hospital who undergo LEJR, collecting enough completed surveys to attain acceptable levels of reliability for such a measure would also be a challenge. Segregating HCAHPS Surveys from patients who had undergone LEJR surgery would often result in a small number of completed surveys as well as demand modifications in well-established survey implementation protocols. Tracing a patient over a 90-day episode through a number of different types of healthcare providers would be very difficult given the de-identified nature of HCAHPS data. Replacement of the HCAHPS Survey measure (NQF #0166) with a physician-based survey would remove the hospital experience from the model.

We have no reason to believe that patients undergoing LEJR differ in their patient experience compared with other HCAHPS-eligible patients in the same hospital. Similarly, we have no evidence that patients who are excluded from the HCAHPS Survey measure (NQF #0166) because of discharge to nursing homes or SNFs have different experience of care than other inpatients, but we have found that consistently contacting and surveying such patients is difficult. Thus, we believe that the HCAHPS Survey is the most viable and practical measure of patient experience of care available for the model at this time.

*Comment:* A commenter suggested using an electronic platform to capture and report the HCAHPS Survey for only the patients in the bundled episodes.

*Response:* The HCAHPS Survey currently permits four modes of survey administration: mail, telephone, mail with telephone follow-up (mixed mode), and Interactive Voice Response. CMS has tested the feasibility of offering an Internet mode for the HCAHPS Survey but determined that issues related to low response rates and poor comparability with the other existing survey modes preclude implementation of a Web-based mode at this time.[82]

*Comment:* Concerned that the proposed measures are disproportionately hospital-focused, many commenters suggested that CMS develop a CAHPS measure that would capture both the in-hospital and post-hospital phases of the 90-day episode for Medicare beneficiaries who had experienced joint replacement surgery and devise a blended CAHPS score across all settings involved with the 90-day episode.

*Response:* CMS patient experience of care surveys are targeted toward providers (hospitals, HHAs, etc.) and assess performance at the provider level. CMS does not possess a survey instrument that tracks hospital inpatients across a 90-day episode or across different types of providers or other settings. Developing such an instrument would be difficult because HCAHPS data submitted to CMS by hospitals or their survey vendors are patient de-identified in order to ensure HIPAA compliance. As such, it would not be feasible to link patient-level HCAHPS results to the same patient-level results on other surveys or other measures from other settings or providers.

*Comment:* A commenter requested that CMS publicly report the HCAHPS Linear Mean Roll-up score of all hospitals on a quarterly basis in order for hospitals to be able to understand where they stand on this measure relative to other hospitals and to facilitate hospitals' ability to rapidly improve performance and assess financial risk.

*Response:* We plan to share information with hospitals on their scores on the quality measures included in the model, including the HCAHPS Linear Mean Roll-up score, on an annual basis. Information on performance will be shared with hospitals through their ongoing *Hospital Compare* Preview Reports on an annual basis. Hospital scores on the model measures will be publicly reported on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) on an annual basis. We note that a goal for the CJR model is to align as many quality measure processes (including public reporting) as is reasonably possible with the HIQR program and for this reason we will be publicly reporting HCAHPS Survey measure (NQF #0166) annually instead of quarterly.

*Comment:* A commenter suggested that CMS implement the quality thresholds in performance year 2 or later, especially for HCAHPS, to help hospitals to understand their quality performance compared to the thresholds and allow them time to make meaningful improvements to quality of care.

*Response:* Hospitals participating in the CJR model have had several years of experience with the HCAHPS survey. Since July 2007, hospitals subject to the IPPS annual payment update provisions have been required to collect and submit HCAHPS data in order to receive their full annual payment update (71 FR 48037). Non-IPPS hospitals, such as CAHs, may voluntarily participate in HCAHPS. The incentive for IPPS hospitals to improve patient experience was further strengthened by the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), which specifically included HCAHPS performance in the calculation of the value-based incentive payment in the Hospital Value-Based Purchasing program beginning with October 2012 discharges.

With respect to the HCAHPS Linear Mean Roll-up score measure that CMS has proposed for the model, hospitals began receiving HCAHPS Summary Star Rating in their December 2014 *Hospital Compare* Preview Report. The HLMR is the basis for the HCAHPS Summary Star Rating; see HCAHPS Star Rating Technical Notes at *http://www.hcahpsonline.org/StarRatings.aspx*. While the HLMR is a new calculation from the existing measures, hospitals have been using the HCAHPS survey for many years and have had time to become familiar with it, with their results, and with their standing relative to other hospitals through information presented on the HCAHPS On-Line Web site such as the HCAHPS Percentiles tables (*http://www.hcahpsonline.org/SummaryAnalyses.aspx*). IPPS hospitals have available their HCAHPS scores' relative rank compared to other hospitals participating in the HVBP program. As such, we believe that hospitals are familiar with their individual and relative performance on

[82] Elliott MN, Brown JA, Lehrman WG, Beckett MK, Hambarsoomian LA, Giordano LA, Goldstein E. A Randomized Experiment Investigating the Suitability of Speech-Enabled IVR and Web Modes for Publicly Reported Surveys of Patients' Experience of Hospital Care. *Medical Care Research and Review,* 70(2): 165–184. 2013.

the HCAHPS Survey measure (NQF #0166).

*Comment:* A commenter suggested that the HCAHPS Survey measure (NQF #0166) be removed from the CJR model unless adjusted for socio-economic status.

*Response:* As discussed in our responses to public comments on the Complications measure (NQF #1550), we do not adjust the measure for patients' socio-economic status directly. However, the patient-mix adjustment of HCAHPS survey scores does include an adjustment for patients' self-reported level of education, which is correlated with other SES indicators; see HCAHPS On-Line Web site: *http://www.hcahpsonline.org/modeadjustment.aspx*.

The intent of the HCAHPS survey is to provide a standardized survey instrument and data collection methodology for measuring patients' perspectives of hospital care. In order to achieve the goal of fair comparisons across all hospitals that participate in HCAHPS survey, it is necessary to adjust for factors that are not directly related to hospital performance but do affect how patients answer HCAHPS survey items. These factors include the mode of survey administration and the characteristics of patients in participating hospitals, often referred to as patient-mix.

Patient-mix refers to patient characteristics that are not under the control of the hospital that may affect patient reports of hospital experiences. The goal of adjusting for patient-mix is to estimate how different hospitals would be rated if they all provided care to comparable groups of patients. In developing the HCAHPS patient-mix adjustment (PMA) model, we sought important and statistically significant predictors of patients' HCAHPS ratings that also vary meaningfully across hospitals. The following PMA variables are included in the HCAHPS patient-mix models: Service line (medical, surgical, or maternity care), age, education, self-reported health status, language other than English spoken at home, age by service line interactions, and percentile response order, also known as ''relative lag time,'' which is based on the time between discharge and survey completion. This adjustment approach is grounded in more than ten years of CAHPS research of case-mix/patient-mix adjustment, reflects the input of a wide variety of stakeholders, has been subject to extensive empirical testing, and has been accepted in the peer-reviewed scientific literature.[83]

*Comment:* A commenter stated that the HCAHPS survey represents a significant delay in reporting results and that the reporting time frame does not coincide with the reporting time for the model.

*Response:* The HCAHPS surveys used to construct the HCAHPS Linear Mean Roll-up score measure in the CJR model corresponds to a similar time frame as that proposed for the Complications and Readmissions measures illustrated in Table 17 of the proposed rule (80 FR 41290). We note that the HCAHPS uses a one year performance period closer to the CJR model initiation date in 2016, and therefore we do not believe the proposed one year performance period of July 1, 2015–June 30, 2016 represents a significant delay in reporting results for the CJR model.

*Comment:* Several commenters suggested that inclusion of the HCAHPS Survey measure (NQF #0166) in the CJR model could harm ''essential'' hospitals because hospitals with higher volume of patients admitted through the emergency department may score lower on the HCAHPS survey. Commenters also stated that hospitals with high proportions of Medicaid, Medicare dual-eligible, and uninsured patients would be adversely affected by the inclusion of the HCAHPS Survey measure (NQF #0166) in the model.

*Response:* We have examined the performance of so-called ''safety net'' hospitals, sometimes referred to as ''essential'' hospitals, on the HCAHPS component of the HVBP program. Although we do not have an official definition or designation of ''safety net'' hospital, we understand that a safety net status typically entails one or more of three criteria: High Medicaid share; high proportion of uncompensated patients; and high county-associated poverty rate.

In general, after all HCAHPS adjustments are applied (patient mix and survey mode), we believe that so-called safety net hospitals, as we understand the term perform similarly to other hospitals. The current adjustment approach that CMS employs is both well-validated and necessary to ensure fair comparisons of HCAHPS scores across hospitals. When these adjustments are applied according to the rules currently in place, the performance of safety net hospitals for the HCAHPS portion of HVBP is typical of hospitals in general.

*Comment:* Many commenters stated that there is an inherent bias in the HCAHPS survey that is difficult to adjust for. A few commenters pointed out that California hospitals rank in the bottom quartile of HCAHPS scores.

*Response:* We do not believe that there is an inherent bias in the HCAHPS survey. We do not believe that there is an inherent bias in the HCAHPS Survey. Along these lines, we have noted over the years that some stakeholders believe that patient experience of care surveys are subjective or that patients are unable to judge the quality of care provided (76 FR 26502). However, CAHPS surveys are designed to measure topics where the patient is the best or only source of information. Beginning in 2002, CMS partnered with the Agency for Healthcare Research and Quality (AHRQ), another agency in the federal Department of Health and Human Services, to develop and test the HCAHPS survey. AHRQ and its CAHPS Consortium carried out a rigorous and multi-faceted scientific process, including a public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-state pilot test; extensive psychometric analyses; consumer testing; and numerous small-scale field tests. We provided three opportunities for the public to comment on the HCAHPS survey and responded to over a thousand comments. The survey, its methodology and the results published by CMS are in the public domain.

In May 2005, the HCAHPS survey was endorsed by the National Quality Forum, a national organization that represents the consensus of many healthcare providers, consumer groups, professional associations, purchasers, federal agencies, and research organizations. In December 2005, the federal Office of Management and Budget gave its final approval for the national implementation of the HCAHPS survey for public reporting purposes. The NQF has twice re-endorsed the HCAHPS survey, most recently in 2014. Performance on the HCAHPS survey varies nationally. CMS believes that this variation reflects true differences in patient experience of care, not inherent bias.

*Comment:* A commenter recommended that the HCAHPS survey measures used in the CJR model and the Hospital Value-Based Purchasing program be the same and that the HCAHPS survey measures used to evaluate performance be harmonized across programs.

[83] Elliott, MD, Zaslavsky AM, Goldstein E, Lehrman,WG, Hambarsoomian K, Beckett, MK, Giordano L. The Effects of Survey Mode, Patient Mix, and Nonresponse on CAHPS Hospital Survey Scores.'' *Health Services Research,* 44(2): 501–518. 2009.

*Response:* The HCAHPS survey measures used in the HIQR Program, HVBP program and the model are tailored to reflect the respective purposes of those programs. CMS chose to use the HCAHPS Linear Mean Roll-up score for the model because it efficiently captures the full range of survey responses in a single statistic. The Patient and Caregiver-Centered Experience of Care/Care Coordination Domain score in the HVBP program is more complicated, comprising achievement, improvement and consistency components and entailing a comparison between a baseline year and a later performance year (76 FR 26516). The HIQR Program includes a wider and deeper array of measures and provides more detailed information about HCAHPS survey performance, which may be useful to consumers.

In the CJR model, the HCAHPS survey measures and their relative weighting are very similar to the HVBP program. Both the CJR model and the HVBP program use a four-quarter roll-up of HCAHPS scores and set a threshold of 100 completed HCAHPS surveys for hospital participation (76 FR 26502). The two programs are also similar in that their HCAHPS component is created from the data submitted for the HIQR Program, thus requiring no additional data collection or submission. While there are differences in the HCAHPS survey measures used in the HVBP program and the CJR model, the measures are strongly correlated. Given that the HIQR and HVBP programs and the CJR model all employ the same HCAHPS survey data, patient experience quality improvement efforts targeted toward hospital performance on any one of these programs will redound to the benefit of all programs.

*Comment:* A commenter suggested that a functional measurement, such as HOOS, KOOS or VR–12, replace the proposed HCAHPS measures in the CJR model so to provide a valid assessment of improvement in patient health and status.

*Response:* The HCAHPS survey (NQF #0166) measures hospital inpatients' experience of care. The HCAHPS survey is not a functional measurement. As such, the HCAHPS survey could not be adequately replaced by a functional measurement because these two types of measure assess different aspects of patient care. We note that the CJR model has included the THA/TKA voluntary data submission initiative (section III.D.3.a. of this final rule) which includes functional patient-reported outcome assessment.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to implement the HCAHPS Survey measure (NQF #0166), as it is the best available measure of patient experience of care for hospitals that perform LEJR procedures. Over 4,000 hospitals currently participate in the HCAHPS survey, and the instrument is also familiar to patients. The HCAHPS survey was carefully designed, developed and implemented, is subject to continuous oversight, has been found to meet high standards of reliability and validity, has been endorsed and re-endorsed by the National Quality Forum, and is currently used in both the HIQR and Hospital Value-Based Purchasing programs. We believe that HCAHPS Survey measure (NQF #0166) is a fair and unbiased measure of patient experience of care at all types of hospitals.

We have no reason to believe that patients undergoing LEJR differ in their patient experience compared with other HCAHPS-eligible patients in the same hospital. Similarly, we have no evidence that patients who are excluded from the HCAHPS Survey measure (NQF #0166) because of discharge to nursing homes or SNFs have different experience of care than other inpatients, but we have found that consistently contacting and surveying such patients is difficult. Thus, we believe that the HCAHPS survey is the most viable and practical measure of patient experience of care available for the model at this time. Finally, we are codifying adoption of the HCAHPS Survey measure (NQF #0166) in § 510.400(a)(2).

d. Applicable Time Period

In the proposed rule (80 FR 41283), in order to align as much as is reasonably possible with other CMS hospital quality and public reporting programs in which these three measures are implemented, we proposed for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) performance time periods to be consistent with the HIQR Program, HVBP program and HRRP. We noted that these programs use a 3-year rolling performance period (that is, the applicable period; see section III.D.2.b.(6) of the proposed rule) for the Hospital-level 30-day, all-cause risk-standardized readmission rate (RSRR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551) and the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) measures. We proposed a 3-year rolling performance period for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) because a 3-year performance period yields the most consistently reliable and valid measure results. We also proposed the 3-year rolling performance periods for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) because hospitals are intimately familiar with these measures. We noted that reconciliation payments to hospitals as part of the CJR model are dependent upon both cost and quality outcome measures, and that making reconciliation payments solely based on cost has the potential to lead to reduced access and stinting of care. We stated that in order to address these possibilities the inclusion of performance on outcome measures is critical to ensure access and high-quality care for patients undergoing these procedures, and that the only way to include reliable quality measures in the model upon which to base reconciliation payments for 2016, is to use measures that have a performance period that precedes the start date of the model. We explained that, from a measure reliability and validity perspective, it is imperative to have at least 4 quarters of data for HCAHPS survey measures and 3 years of data for the THA/TKA readmissions and complications measures. We intentionally chose outcome and patient experience measures for which hospitals that are already financially accountable in other IPPS programs. Consequently, the performance periods are the same periods for the THA/TKA Readmissions and Complications measures between the model, HIQR Program, HVBP program and HRRP. For the HCAHPS survey measures, there is overlap with the performance periods for the model and the HIQR Program.

We stated our belief that it is appropriate and necessary to use performance periods that precede the start date of the model because: (1) There is no downward payment adjustment associated with the model; (2) hospitals are already familiar with these measures as part of the HIQR Program, HVBP program, and HRRP; and (3) hospitals are already held financially accountable for these measures. For the HCAHPS Survey measure (NQF #0166), we would continue to use a 4 quarter performance period as in the HIQR Program, but would not align with the HIQR Program performance period. We shared how we

initially considered using the same HIQR Program performance period for the HCAHPS Survey measure (NQF #0166), but realized that should we use the same HIQR Program performance periods for the model, other model timeframes and policy goals would not be met. We indicated such policy goals like calculating reconciliation payment adjustments in a timely fashion during the 2nd quarter of each year might not be met, and we also noted that HCAHPS survey results are not available until the 3rd quarter of each year. For these reasons, we did not propose that the HCAHPS survey performance period follow the HIQR Program performance periods. We also proposed that HCAHPS survey scores be calculated from 4 consecutive quarters of survey data. We closed the proposal by indicating that public reporting of HCAHPS survey results are also based on 4 quarters of data (79 FR 50259).

The following is a summary of the comments received and our responses.

*Comment:* Some commenters supported the three-year rolling period of performance for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). Others did not support the three-year rolling performance period for these two measures and expressed concerns because—(1) With a start date of January 1, 2016, hospitals would only have three months to improve on the performance for the three measures; (2) the three-year rolling performance period does not coincide with the 12-month performance period used by the CJR model to determine the reconciliation payment; (3) a three-year rolling performance period exacerbates the lack of correlation between the CJR model 12-month performance and the measure performance periods; (4) the three-year rolling performance period includes a significant amount of data that pre-date the start of the model proposed for January 1, 2016 ; and (5) the potential impact that a single year of poor performance may have on the subsequent 2 years of performance. Most commenters recommended that the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) coincide with the CJR model 12-month performance period used to determine the reconciliation payment.

*Response:* We appreciate the concerns regarding the use of the three-rolling performance period for the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551). We note that these measures rely on administrative claims data that are at least a year old because providers have up to one year to submit administrative claims for payment and that the measures are designed to include only administrative claims that are final action claims. The measures use final action claims in order to ensure consistency in the type of hospital data is used in the measures. Additionally, use of performance periods up to 3 years ensures adequate sample size for administrative claims based measures. For these reasons we believe it is reasonable to use a 3 year-rolling performance period, and in order to have sufficient data for the first year of the model use of data that precedes the start of the CJR model will help to provide a reliable estimate of a hospital's performance on the THA/TKA Complications measure (NQF #1550).

Regarding the concern that hospitals would only have 3 months to improve on the performance for the three proposed measures, we note for the HIQR Program that the THA/TKA Complications measure (NQF #1550) and the THA/TKA Readmissions measure (NQF #1551) were finalized in the FY 2013 IPPS/LTCH Final Rule (77 FR 53534) for implementation in FY 2015, and the most updated HCAHPS Survey measure (NQF #0166) was finalized in FY 2014 IPPS/LTCH final rule (78 FR 50807) and in the HVBP program (76 FR 26502). We therefore believe hospitals have received ample time to identify ways in which to improve their performance on these three measures. Finally, we specifically considered this aspect of the measures knowing that hospitals were familiar with these measures and had more than likely instituted quality improvement activities in order to perform well on these measures.

Regarding the request to use a 12-month performance period, we note that from a measure reliability perspective—(1) A rolling 3-year performance period consistently identifies more eligible index admissions for each hospital as compared to a single year of hospital performance data or a 3-month period of data. Using a larger number of index admissions improves the precision of the estimation of each hospital's results for the THA/TKA Readmissions measure (NQF #1551) and THA/TKA Complications measure (NQF #1550). We note that if we were to have a 12-month performance period, the reliability of these measure results would become questionable; (2) a rolling 3-year performance period provides larger sample sizes, which will allow the calculation of measure results that are better able to more meaningfully distinguish hospital performance; and (3) in order to provide meaningful measures results that use claims data, we believe it is important to use claims data that has completed the appropriate opportunities for appeal and correction through the CMS administrative claims submission process. Without opportunities for hospitals to correct claims errors, the measure results may not be valid and reliable for making quality improvements in hospital processes. For these reasons we believe that having a rolling 3-year performance period is reasonable for the THA/TKA Complications measure (NQF #1550). We note that the THA/TKA Readmissions measure (NQF #1551) is not finalized for the CJR model.

After review of public comments, we are finalizing the three-year rolling performance period as proposed for the THA/TKA Complications measure (NQF #1550). Similarly, for the HCAHPS Survey measure (NQF #0166), we are finalizing our proposal that the HCAHPS survey scores be calculated from 4 consecutive quarters of survey data and that publicly reported HCAHPS results are based on 4 quarters of data (79 FR 50259). Since we are not finalizing the THA/TKA Readmissions measure (NQF #1551), as discussed in section III.D.2.b. of this final rule, we will not be finalizing any applicable period for this measure.

3. Possible New Outcomes for Future Measures

a. Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(1) Background

In the proposed rule (80 FR 41284), we stated that part of our goal to move towards outcome measures that assess patient-reported outcomes, we had begun development on a measure to assess improvement in patient-reported outcomes following THA/TKA procedures. We shared that the Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (hereinafter referred to as ''THA/TKA patient-reported outcome-based measure'') is currently under development. In our proposal, we shared that we specifically chose to focus on THA/TKA procedures since THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (for example, pain, mobility, and quality of life) can be

measured in a scientifically sound way and are also influenced by a range of improvements in care.[84] [85] [86] We also shared that THA/TKA procedures are specifically intended to improve function and reduce pain, making patient-reported outcomes the most meaningful outcome metric to assess for these common, costly procedures. We outlined that patient-reported outcomes will be assessed separately for THA and TKA procedures, though these results may be combined into a single composite measure for reporting, and indicated that we would refer to a single measure, while acknowledging the possibility of two measures, one for THA patients and one for TKA patients.

In the proposed rule we provided background on measure development, and shared our discovery that in order to complete measure development, we would need access to a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data set that is also consistently collected at the hospital-level and contains risk variables identified by orthopedists. Further, we noted that our rationale for requesting access to a national THA and TKA inpatient surgical procedures patient-reported data source was twofold—(1) A national data source would provide us with hospital-level data representative of the total number of THA and TKA procedures performed in hospitals, as well as representative data on hospital-level case-mix; and (2) access to a national THA and TKA inpatient surgical procedures patient-reported data source would allow us to assess and identify a set of parsimonious data elements that will minimize the data collection burden by patients, physicians and hospitals. We shared our belief that—(1) Access to such data would allow for completion and testing of the current measure under development so that it could be appropriately used for nationwide hospital performance evaluation; and (2) the model provides a unique opportunity to resolve these measure development issues through the collection of THA and TKA patient-reported outcome data. We stated that access to this data through the model would address the following:

- Current data sources are not consistently collected nor collected in a uniform process and in a standardized format (that is, data elements are not consistently defined across different data sources). We note that currently available data sources tend to be limited to single hospitals or regional registries which are associated with complex data access sharing requirements.
- Current lack of uniform hospital-level data that can be used in measure development.
- Lack of incentive for physicians and hospitals to collect patient-reported outcome data such as that through the model's financial incentives associated with voluntary data submission.
- Current lack of a technically simple and feasible mechanism for hospitals to submit patient-reported data to CMS. This model would help create and optimize such a mechanism, potentially enabling future measure implementation.

Additionally we stated that the voluntary data collection initiative in the model would provide an opportunity to collect data from the patient's perspective, data that is necessary to finalize and test the measure specifications, including the risk model. In the proposed rule, we shared how access to this national representative voluntarily submitted data would enable us to do the following:

- Determine a parsimonious set of risk factors that are statistically adequate for risk adjustment for patient-reported outcome.
- Examine the differences in hospital performance related to different components in the patient-reported outcome (such as functional status, pain, etc.) to finalize the statistical modeling methodology for risk adjustment.
- Evaluate the reliability of the patient-reported outcome measure.
- Examine validity of the patient-reported outcome measure upon finalization of the risk adjustment model via potential testing methods such as face validity testing with national experts, comparing the measure results to similar results based on other data sources if feasible, etc.

We also addressed the importance of encouraging participation with voluntary data submission of patient-reported outcome data, so we proposed to reward voluntary participation in submission of THA/TKA patient-reported outcome-based measure data as outlined in section III.D.3.a. of the proposed rule. We also indicated that we would not publicly report the THA/TKA voluntary data.

Finally, we shared our intention to use a fully tested and completed THA/TKA patient-reported outcome-based measure in CMS models or programs when appropriate. We stated that if there is a decision to implement the fully developed THA/TKA patient-reported outcome-based measure, such as in the CJR model, we would propose to adopt the measure through notice-and-comment rulemaking. We also referenced draft measure specifications in the Downloads section of the Measure Methodology Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

The following is a summary of the comments received and our responses. Please note the use of the following acronyms: (1) Patient-reported outcome will be noted as PRO; (2) patient-reported outcome measure (PROM) is a patient-reported outcome survey instrument; and (3) patient-reported outcome-based performance measure will be noted as PRO–PM. These terms are consistent with the National Quality Forum Patient Reported Outcomes (PROs) in Performance Measurement, January 10, 2013 (available at: *http://www.qualityforum.org/Publications/2012/12/Patient-Reported_Outcomes_in_Performance_Measurement.aspx*).

*Comment:* Many commenters supported CMS's goal to measure and improve patient-reported outcomes. Many commenters supported the PRO data voluntary reporting proposal. Multiple commenters specifically urged CMS to adopt the proposal to gather PRO data for the purpose of completing development of the hospital-level THA/TKA PRO–PM. A commenter supported linking the reconciliation payment to quality performance. A commenter supports the financial incentive for hospitals that participate in the voluntary data collection initiative.

*Response:* For a detailed discussion of the payment perspective for use of the THA/TKA voluntary PRO data in determining reconciliation payment, including our responses to public comments, we refer readers to section III.C.5.b.(5)(b) through III.5.b.(5)(c) of this final rule.

*Comment:* Several commenters recommended that CMS fully develop the PRO–PM before implementing the

[84] Monticone M, Ferrante S, Rocca B, et al. Home-based functional exercises aimed at managing kinesiophobia contribute to improving disability and quality of life of patients undergoing total knee arthroplasty: A randomized controlled trial. *Archives of physical medicine and rehabilitation.* Feb 2013;94(2):231–239.

[85] Galea MP, Levinger P, Lythgo N, et al. A targeted home- and center-based exercise program for people after total hip replacement: A randomized clinical trial. *Archives of physical medicine and rehabilitation.* Aug 2008;89(8):1442–1447.

[86] Moffet H, Collet JP, Shapiro SH, Paradis G, Marquis F, Roy L. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single blind randomized controlled trial. *Archives of physical medicine and rehabilitation.* Apr 2004;85(4):546–556.

measure's use in a payment model. Several commenters stated that the proposed quality measures are not rigorous in the way in which they were developed and the selection of specifications such as PROM instruments in the PRO–PM.

*Response:* We note that the purpose of this voluntary PRO and risk variable data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary and limited risk variable data to assess hospitals' performance, but instead will use the voluntary submitted data to complete development of a PRO–PM measure for future use in the CJR model. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary PRO and risk variable data submission by rewarding hospitals that successfully submit THA/TKA voluntary and risk variable data. We believe our measure development process is rigorous and transparent. We created a list of candidate PROM instruments following an environmental scan and literature review. Our measure development contractor convened a Technical Expert Panel through a public process. Based on input from the Technical Expert Panel and a public comment period, we proposed validated, non-proprietary PROMs that have been tested in patients undergoing THA/TKA or, in the case of the PROMIS-Global, had undergone rigorous testing during development with plans to test in patients undergoing THA/TKA. The final rule is limited to a voluntary PRO data collection initiative that will inform our standard measure development process set forth in NQF guidance for outcome measures,[87] CMS Measures Management System (MMS) guidance,[88] and the guidance articulated in the American Heart Association Statement ''Standards for Statistical Models Used for Public reporting of Health Outcomes.'' [89] Once finalized, the THA/TKA PRO–PM that will be developed using the voluntary PRO and risk variable data will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status. The application of a patient-reported outcome measure in the CJR model is important for providers to understand where they can adjust or change their processes in order to improve the care they are providing. Having a PRO–PM measure will also provide important information about provider care for the beneficiaries and their families and caretakers.

*Comment:* A commenter recommended that CMS facilitate collaboration among hospitals to share best practices for PRO data collection.

*Response:* We agree with the commenter's recommendation. We intend to support hospitals that choose to collect PRO data as part of the CJR model by providing education and dissemination of successful practices.

*Comment:* A commenter recommended reporting separate total hip and knee arthroplasty PRO–PMs.

*Response:* We appreciate the recommendation to report separate total hip and knee arthroplasty measures. As indicated on pages 14 and 16 in the Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure(s) Phase 3 Measure Methodology Report posted on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*, we agree with the commenter that hospital performance for the care of THA and TKA patients be assessed using separate PRO–PMs and intend to develop a THA/TKA PRO–PM that assesses THA and TKA PROM results separately and then combine them into a composite score that preserves the distinctions in clinical outcomes between these patient groups if needed for adequate sample sizes to ensure stable performance estimates. The PRO-based measure remains under development, and this input will inform future measure development work.

*Comment:* A commenter noted a high response rate within their group, and cautioned that poor response rates will undermine validity and comparisons across settings.

*Response:* We appreciate the commenter's support of measuring PROs and concerns about obtaining adequate PROM response rates and applaud the commenter's success in this realm. We encourage the commenter to share any insights regarding optimizing PRO response rates with CMS to further this important measurement effort. We appreciate the concern that poor response rates will undermine the validity of the data collected and the ability to compare outcomes across settings. We note that section III.D.3.a.(9) of this final rule addresses this concern by finalizing a different definition of successful THA/TKA voluntary data submission.

*Comment:* Some commenters recommended that the THA/TKA PRO–PM should be tested, reviewed, and endorsed by the NQF.

*Response:* We plan to submit the THA/TKA PRO–PM to the appropriate NQF project upon completion of measure development.

*Comment:* A commenter urged CMS to validate the risk adjustment methodology before hospitals' results on the PRO–PM are reported on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) or the *Physician Compare* Web site (*https://www.medicare.gov/physiciancompare/*).

*Response:* We note that the THA/TKA PRO–PM is currently under development. We plan to validate the risk adjustment methodology prior to implementing the measure into any public reporting program. As noted in the proposed rule (80 FR 41290), the THA/TKA voluntary data will not be publicly reported, but instead a symbol will used to acknowledge CJR model hospitals that successfully submitted the voluntary data.

*Final Decision:* After consideration of the public comments, we wanted to express our appreciation for the support for this THA/TKA voluntary PRO data submission initiative. As with all of our measures in development, when appropriate, they are reviewed by NQF for endorsement and by the NQF Measure Applications Partnership for implementation in programs. Finally, we appreciate the recommendations to facilitate collaboration among hospitals to share best practices for PRO data collection and, as stated previously, will be looking for ways to support this recommendation. We are finalizing the THA/TKA voluntary PRO and risk variable data submission initiative as previously discussed.

(2) Data Sources

In the proposed rule (80 FR 41285), we shared that this measure is under development, and we proposed to reward participant hospitals that volunteer to submit provider- and patient-level data elements. We shared our observation that currently, there is

[87] National Quality Forum. Measure Evaluation Criteria and Guidance. April 2015. Available at: *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx.* Accessed on September 22, 2015.

[88] Measures Management System Overview.2015; *http://www.cms.gov/Medicare/Quality-Initiatives Patient-AssessmentInstruments/MMS/index.html ?redirect=/MMS/19_MeasuresManagementSystem Blueprint.asp.* Accessed September 8, 2015.

[89] Krumholz H, Brindis R, Brush J, *et al.* Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation. *Circulation.* Jan 24 2006;113(3):456–462.

little uniformity across hospitals regarding collection of specific provider- and patient-level data elements that are used to assess patient outcomes after THA and TKA inpatient procedures. We also shared for the voluntary data submission for the THA/TKA patient-reported outcome-based measure initiative, our goal to identify a uniform set of provider- and patient-level data elements that are accurate, valid, and reliable pieces of information that can be used in the determination of improvement in various patient characteristics like those previously listed (that is, pain, mobility, and quality of life). We also shared our goal to minimize patient, provider and hospital burden associated with data collection and submission of provider- and hospital-level data elements, by proposing a variety of data sources for measure development. We provided the following three categories of anticipated data sources for public comment:

- Patient-reported data.
- Administrative claims-based data.
- One or both physician-reported and electronic health record data.

As a way to minimize burden on patients, providers, and hospitals we proposed to request that participant hospitals provide administrative claims-based data whenever possible; we also requested that participant hospitals submit either hospital documentation, chart abstraction, or abstraction from the electronic health records. The list of proposed data elements are summarized in the proposed rule (80 FR 41285).

Finally, we stated that as the measure continues to undergo development that the list of data elements may be simplified consistent with our previously stated goal in this section entitled Data Sources, that we intend to identify a uniform set of provider- and patient-level data elements that are accurate, valid and reliable pieces of information that can be used in the determination of improvement in various patient-reported outcomes like those previously listed (that is, pain, mobility, and quality of life). We shared our anticipation that via public comment and experience with the voluntary data submission, that the set of data elements listed previously will be simplified.

In accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we proposed to request that participant hospitals submit the data specified in the request, which we would limit to the minimum data necessary for us to conduct quality assessment and improvement activities. Regarding the process for data collection, we proposed the THA/TKA voluntary data will be submitted to and collected by a CMS contractor in a manner and format similar to existing CMS data submission processes. For example, CMS would supply applicable hospitals with a file template and instructions for populating the file template with data and submitting the data; the hospitals will populate the template, log in to a secure portal, and transmit the file to the appropriate CMS contractor; the CMS contractor would also match the submitted data to Medicare administrative claims-based data and calculate completeness for determination of the reconciliation payment as noted in section III.C.5. of the proposed rule (or validated subscales or abbreviated versions of these instruments). We stated our belief that participation in the submission of THA/TKA—voluntary data will provide the minimum information we would need that would inform us on how to continuously improve the currently specified measure in development.

Finally, we noted that some of these data elements are closely aligned with data elements in electronic clinical quality measures submitted by eligible professionals for the Medicare EHR Incentives Program for Eligible Professionals. Specifically these EHR Incentives Program measures for eligible professionals are: (1) Functional Status Assessment for Knee replacement (CMS 66); and (2) Functional Status Assessment for Hip replacement (CMS 56). We refer reviewers to CMS.gov EHR Incentives Program 2014 Eligible Professional June 2015 zip file update at *http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/eCQM_2014_EP_June2015.zip* for full measure specifications. We stated our belief that it is possible that many health IT vendors are already certified to capture, calculate and report these provider-level measures of functional status on total knee and total hip arthroplasty, and therefore we anticipate that the provider-level data elements that are identical to the THA/TKA patient-reported outcome voluntary data elements previously listed may not be as burdensome for the CJR model participant hospitals to voluntarily submit.

The following is a summary of the comments received and our responses. We received many public comments on the Data Sources section and have divided the public comments and our responses into two categories—(1) Public comments not specifically related to the proposed PRO and risk variable data elements (80 FR 41825); and (2) public comments specifically related to the proposed PRO and risk variable data elements.

The following are public comments made that are not specifically on the proposed instruments (80 FR 41825) and our responses.

*Comment:* A commenter questioned whether CMS will include economic or clinician-reported outcomes in addition to clinical outcomes.

*Response:* We will be capturing generic health-related quality of life assessments with the VR–12 and PROMIS-Global, which will supplement the clinical outcomes of the HOOS/KOOS Jr. or specified HOOS/KOOS subscales (see Table 28). We will not be capturing patient-reported economic or clinician-reported outcomes. The purpose of this voluntary PRO data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary data to assess hospitals' performance during Years 1–3 of the CJR model, but instead will use the submitted data to complete development of a PRO–PM measure. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary data submission by rewarding hospitals that successfully submit THA/TKA voluntary data during Years 1–3. Comparisons with other outcome measures can be made when such a measure is fully developed. Once finalized, the THA/TKA PRO–PM that will be developed using the voluntary PRO and risk variable data will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status.

*Comment:* A few commenters recommended that CMS use existing measures, such as Functional Status Change for Patients with Knee Impairments (NQF #0422) and Functional Status Change for Patients With Hip Impairments (NQF #0423), both of which are stewarded by Forum on Therapeutic Outcomes, Inc. (FOTO), to measure patients' functional status in the CJR model. The commenters stated that these NQF-endorsed measures are in the public domain, are economical and are not burdensome to patients or clinicians. The commenters noted that these measures are already in use in the PQRS and that developing a new measure instrument is an imprudent use of government resources.

*Response:* To the best of our knowledge, the FOTO measures (NQF #0422 and #0423) are not specifically tested in THA/TKA patients, but rather medical patients with hip or knee complaints who initiated rehabilitation

treatment. We also note that, to the best of our knowledge, the FOTO measures lack data demonstrating the validity in the elective primary THA/TKA patient population. Furthermore, although the FOTO measures are NQF-endorsed and in the public domain, to the best of our knowledge, the measures can only be reported using a proprietary web-based patient assessment system to collect the data. In keeping with our goal to minimize burden for hospitals and after receiving input in previous rulemaking urging CMS to avoid adoption of rules that require or incentivize that hospitals use proprietary tools, such as interoperability standards (71 FR 68198), or pay to participate in a specific registry (73 FR 48609), we have decided not to pursue these measures. As such, we prioritized the use of non-proprietary PROM instruments as part of the PRO data collection initiative. Finally, we note that we are not developing a PROM instrument and therefore disagree that CMS is acting unwisely with government resources. On the contrary, we have investigated using instruments that are in the public domain and are non-proprietary. The purpose of this voluntary PRO and risk variable data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary and risk variable data to assess hospitals' performance, but instead will use the voluntary submitted data to complete development of a PRO–PM measure. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary and risk variable data submission by rewarding hospitals that successfully submit THA/TKA voluntary data. We note that the THA/TKA voluntary and risk variable data will assess hospital quality of care for patients undergoing elective primary THA/TKA procedures. Once finalized, the THA/TKA PRO–PM that will be developed using the voluntary PRO and risk variable data will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status.

*Comment:* A commenter stated developing a new measurement instrument for this project and specifically for THA and TKA patients is unnecessary, time-consuming, and costly.

*Response:* To clarify, we are not developing a PROM instrument. We will use existing, validated, non-proprietary PROM instruments for a voluntary PRO data collection for the development of a future hospital-level patient-reported outcomes performance measure.

*Comment:* A few commenters recommended expanding the PRO–PM to capture patients' experience in PAC settings.

*Response:* The purpose of this voluntary PRO data collection is to complete the development of a THA/TKA PRO–PM. We will use the THA/TKA voluntary data to complete development of a PRO–PM measure. We note that, the intention of the future PRO–PM measure is to capture patient-reported outcomes that are meaningful to patients undergoing elective primary THA/TKA procedures. As the purpose of a majority of elective primary THA/TKA procedures is the long-term improvement in pain and functional outcomes, we believe that measuring such outcomes and attributing them to the hospital where the procedure is performed is most appropriate. We will consider adapting any future measure to other care settings as appropriate.

*Comment:* A few commenters recommended that CMS consider performance-based measures of function, such as the 6-minute walk test.

*Response:* We appreciate the commenter's input. The decision to focus on patient-reported assessments rather than functional performance assessment reflects CMS's commitment to patient-centered care. The validated PRO instruments that are proposed for voluntary data collection reflect outcomes meaningful to patients. A functional performance assessment offers an objective evaluation of function, but may not accurately reflect the patient's own experience and health status; one individual may experience a marked improvement in their 6-minute walk test after THA, but they may be unable to rise from a seated position or bend over to tie their shoes or pick up an object, which are critical functional outcomes not necessarily captured by a 6-minute walk test. Once fully developed, the THA/TKA PRO–PM, which will be developed using the voluntary PRO and risk variable data and will capture functional outcomes such as those stated in the text (ability to rise from a seated position or bend, to tie their shoes), will be incorporated into the CJR model in the future, through rulemaking, and therefore will address public comments strongly recommending the model include a measure of functional status.

*Comment:* A commenter expressed concern that data obtained from PROMs are mostly comprised of patient-subjective responses.

*Response:* We believe that patient-reported outcomes are a critical type of outcome needed for healthcare quality assessment. PROMs are intended to capture patients' self-assessments of their health. They provide a direct way to capture patients' experience of care and its results. PROMs can assess multiple health domains, including physical health, emotional well-being, and social functioning, through measuring outcomes relevant to each domain, such as symptoms, functional status, and mental status. As a result, they provide rich information on how care affects multiple dimensions of patients' well-being. PROMs can provide timely information on patient health status, function, and symptoms over time that can be used to improve patient-centered care and inform clinical decision-making.[90]

*Comment:* A commenter recommended using the PRO data to develop three registries: Hip implants, knee implants, and surgeon-specific performance.

*Response:* The purpose of this voluntary PRO data collection is to complete the development of a THA/TKA PRO–PM. We will not use the THA/TKA voluntary PRO and risk variable data to assess hospitals' performance, but instead will use the voluntary submitted data to complete development of a PRO–PM measure. Finally, we would like to use the innovative strategy to encourage THA/TKA voluntary and risk variable data submission by rewarding hospitals that successfully submit THA/TKA voluntary data. Once finalized, the THA/TKA PRO–PM, that will be developed using the voluntary PRO and risk variable data, will be incorporated into the CJR model through rulemaking to address public comments strongly recommending the model include a measure of functional status. There are several existing regional and national registries, many in collaboration with surgical specialty societies, which are collecting data on a variety of outcomes and information about patients undergoing THA/TKA procedures.

*Comment:* Several commenters suggested that CMS work with joint registries to which hospitals voluntarily report to reduce burden by using existing mechanisms of data collection. A commenter suggested CMS partner with the California Joint Replacement Registry (CJRR). Other commenters suggested CMS partner with the

[90] Cella D, Hahn EA, Jensen SE., Butt Z, Nowinski CJ, Rothrock N. *Methodological Issues In The Selection, Administration And Use Of Patient-Reported Outcomes In Performance Measurement In Health Care Settings: Final Manuscript.* Prepared for the National Quality Forum Consensus Development Project on Patient-Reported Outcomes. September 28, 2012.

American Joint Replacement Registry (AJRR).

*Response:* We note that we have been collaborating with CJRR and AJRR as part of the development of the THA/TKA PRO–PM. However, at this time we are not requiring hospitals to pay to participate in specific registries as part of the PRO data collection initiative. We note that previous public comments regarding the use of proprietary registries urged CMS to avoid adoption of policies that require or incentivize hospitals to join a specific registry (73 FR 48609) in order to provide data for CMS quality and payment programs.

*Comment:* Several commenters requested that CMS make patient-reported data collection a mandatory component of the CJR model. Some of the commenters suggested significantly increasing incentives for patient-reported data collection under the proposed voluntary approach. Commenters suggested a phase-in approach to fully implementing the fully developed patient-reported outcome performance-based measure as part of the CJR model.

*Response:* We appreciate the suggestion to make the THA/TKA voluntary data collection mandatory and may consider it as we continue to improve the model. We did not make this initiative to collect THA/TKA PRO data mandatory for the following reasons: (1) This is a measure in development; and (2) we sought not to burden hospitals with additional financial costs while testing a new payment structure. We believe this is consistent with a phase-in approach to fully implementing the fully developed patient-reported outcome performance-based measure as part of the CJR model.

The following are public comments that specifically address the proposed instruments and our responses include the following:

*Comment:* A few commenters recommended the use of Oxford Hip and Knee Scores (OHS/OKS) which are two separate PROM instruments. A commenter suggested the Oxford PROMs have been evaluated independently and found to be the most reliable systems for assessment of hip and knee replacement.

*Response:* We appreciate the commenter's recommendation to use the OHS/OKS. We considered the OHS/OKS as candidate PROM instruments. In the early phases of measure development, we created a list of candidate PROMs through an environmental scan and literature review. Then, a Technical Expert Panel convened by our measure development contractor reviewed the list of candidate PROMs. The Technical Expert Panel questioned the usability of the OHS/OKS and expressed concern over their proprietary nature, and recommended removing them from the list of candidate PROMs. The condition-specific PROMs recommended by the Technical Expert Panel and proposed for this model represent validated, non-proprietary PROMs that have been tested in patients undergoing THA/TKA. For additional rationale for the selected PROM instruments, we refer readers to page 20 of the Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure(s) Phase 3 Measure Methodology Report posted on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

*Comment:* A few commenters requested that CMS use non-proprietary (or open access) PROM instruments to avoid requiring purchasing and maintenance costs.

*Response:* We agree with the commenters and note that the proposed PROM instruments are non-proprietary instruments. We received similar input in previous rulemaking urging CMS to avoid adoption of rules that require or incentivize that hospitals use proprietary tools, such as interoperability standards (71 FR 68198), or pay to participate in a specific registry (73 FR 48609). As such, we prioritized the use of non-proprietary PROM instruments as part of the PRO data collection initiative.

*Comment:* A commenter shared, and did not suggest, a list of THA PROM instruments currently in use at their health system: VR–12, HOOS, UCLA Activity Level Rating Form, and Modified Harris Hip Form. The commenter also shared a list of instruments that are in development to be used across their health system's orthopedic sites: FAAM Sport, quick DASH, Forgotten Joint Score, KOOS, Knee Society Score, Neck Disability Index, SRS–22, DASH, Pelvic Floor Disability Inventory-20, and PODCI.

*Response:* We appreciate the list of instruments in use at the commenter's health system. We note that we reviewed many of these instruments, as did the Technical Expert Panel convened by our measure development contractor. Among the listed instruments, the Technical Expert Panel strongly favored the VR–12, HOOS, and KOOS because of their appropriateness for the primary elective THA/TKA patient population. We provide further rationale on our selection of PROM instruments in response to other comments within this rule. Nonetheless, we applaud the commenter's use of PROM THA instruments to assess quality and patient outcomes on those under their care. We also appreciate the added knowledge shared by the commenters regarding their instruments under development.

*Comment:* A commenter recommended obtaining PROM data as early as 90 days postoperative. Another commenter recommended obtaining postoperative PROM data not less than 6 months after discharge for the THA or TKA. A commenter recommended obtaining postoperative PROM data not less than nine months after discharge for the THA or TKA.

*Response:* The window for post-operative data collection was selected based upon consultation with national clinical experts and empiric data from literature indicating that patients continue to improve until approximately 180 days post-operatively and have generally experienced the full benefit of their surgery by 270 to 365 days after THA/TKA. Moreover, the post-operative data collection period between 270 to 365 days aligns with one-year follow-up visits and thus, addresses the concern of low post-operative PROM completion rate if administered prior to 270 days. For additional rationale and citations, we refer readers to page 18 in the Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure(s) Phase 3 Measure Methodology Report posted on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

*Comment:* A commenter recommended that CMS consider using the Forgotten Joint Knee Score. Another commenter recommended the SF–36.

*Response:* We considered the SF–36 and SF–12, a shorter version of the SF–36, as alternative to the VR–12, as did the Technical Expert Panel convened by our measure development contractor. The Forgotten Joint Knee Score had not been published at the time of our literature review and environmental scan and was not raised by the Technical Expert Panel as an option. The SF–36, SF–12 and the Forgotten Joint Knee Score are all proprietary instruments, and after consideration of these instruments and prior situations in which proprietary tools or databases were suggested and not found favorable with the public, we decided on the non-

proprietary VR–12, PROMIS-Global, HOOS Jr. and KOOS Jr. (or HOOS/KOOS subscales listed in Table 28). We believe using non-proprietary instruments will not place an added financial burden on CJR model participant hospitals.

*Comment:* A commenter requested that CMS develop a ''gold standard'' PROM instrument that is easily administered and has a small and targeted number of questions.

*Response:* We appreciate the commenter's recommendation, and we note that we are not currently developing a PROM instrument. CMS is developing a PRO–PM outcomes measure and not the instrument to collect functional outcome data. The purpose of this voluntary PRO data collection is to collect the data required to develop the future PRO-based performance measure that will assess hospital quality of care for patients undergoing elective primary THA/TKA procedures. We believe that there are numerous instruments already available in the public domain, which through our Technical Expert Panel have been recommended for our consideration in the THA/TKA PRO–PM in development.

*Comment:* A commenter supported the proposal to collect the VR–12 and PROMIS Global instruments. Several commenters supported the proposal to use the HOOS and KOOS instruments. Many commenters recommended allowing participating hospitals to submit either the VR–12 or the PROMIS Global instruments to satisfy the PRO data collection requirement because the proposed required PRO data elements for the voluntary PRO data collection are too burdensome. Several commenters specifically recommended PROMIS Global, but not VR–12 because it is duplicative and does not add value.

*Response:* We appreciate the commenters' input on the PRO voluntary data collection proposal. We appreciate the support of our proposal to collect the VR–12 and PROMIS Global instruments and the HOOS or KOOS instruments.

We also appreciate the public comments that indicated that the proposed required PRO data elements for the voluntary PRO data collection are too burdensome. We acknowledge evidence indicating that the PROMIS-Global and VR–12 are highly correlated.[91] Based on the supporting evidence, and in response to public comments, we will allow CJR model hospital participants to collect and submit either the VR–12 or the PROMIS-Global for purposes of determining ''successful'' voluntary patient-reported outcome data collection. These data must be collected both pre-operatively (90 to 0 days prior to the THA/TKA procedure) and post-operatively (270 to 365 days after the THA/TKA procedure). As hospitals may already be collecting VR–12 or PROMIS-Global data for other purposes, we believe providing this option for submitting to CMS data using either instrument is the least burdensome option for hospitals.

*Comment:* Several commenters supported CMS's consideration of an abbreviated version of HOOS/KOOS. Commenters recommended the HOOS/KOOS pain and function subscales, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), or the HOOS Jr/KOOS Jr as possible alternatives to the full HOOS/KOOS, and cautioned that both pain relief and functional gain are important outcomes and that both should be measured. Specifically, a joint statement from multiple surgical specialty societies indicated new data validating shortened versions of the HOOS/KOOS instruments in THA/TKA patients. These shortened versions have been named the HOOS Jr. (6 items) and KOOS Jr. (7 items); both shorter versions are highly responsive in the THA/TKA patient population (standardized response means 1.7 to 2.4). In addition, the HOOS/KOOS Jr. were highly correlated with the Pain and Function, Daily Living subscales of the full HOOS/KOOS instruments and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Spearman's correlation 0.80–0.94). These findings on the HOOS/KOOS Jr. were presented at the 2015 AAOS Annual Meeting [92] and 2015 International Society of Arthroplasty Registries (ISAR) Annual Meeting, respectively.

*Response:* We note that the WOMAC is a proprietary instrument. As previously discussed, we sought not to burden hospitals with a proprietary instrument and therefore did not consider this instrument.

Regarding the HOOS/KOOS PROMs, we appreciate the consistent comment that the HOOS/KOOS instruments for this specific voluntary PRO data submission proposal are too burdensome. These instruments were recommended by a diverse, nationally convened Technical Expert Panel assisting our contractor with the development of this measure. During review of these instruments, the Technical Expert Panel acknowledged the length of the instruments as a limitation for its use. For reasons outlined in prior responses, the Technical Expert Panel recommended these instruments over shorter, proprietary joint-specific PROM instruments. We noted in review of the public comments, a joint statement from multiple surgical specialty societies indicated new data validating shortened versions of the HOOS/KOOS instruments in THA/TKA patients. Further, the HOOS/KOOS instruments were originally developed to create five specific subscale scores: Pain, other Symptoms, Function in daily living (ADL), Function in sport and recreation (Sport/Rec) and knee related Quality of life (QOL) (*http://www.koos.nu/*).

Based upon the fact that the HOOS/KOOS instruments were developed to create specific subscale scores intended for independent scoring as well as additional evidenced-based data supporting the use of meaningful information on THA/TKA PROMs gathered in substantially less burdensome, non-proprietary instruments and broadly supported by the orthopedic community, we believe it is reasonable to replace the previously proposed collection of the full HOOS or KOOS survey with the shorter HOOS Jr. and KOOS Jr. or with the following list of HOOS and KOOS subscales.

For hospitals seeking to voluntarily collect and submit PRO data on THA patients, we would require collection and submission of all of the following for purposes of determining ''successful'' voluntary patient-reported outcome data collection:

- Either VR–12 or PROMIS-Global [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure], the revised list of risk variables [Table 28, collected only pre-operatively (90 to 0 days prior to the THA procedure)], and
- Either (A) the HOOS Jr. (6 items total) [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure] or (B) the original HOOS Pain Subscale (10 items), AND the original HOOS Function, Daily Living Subscale (17 items, for a total of 27 items) [collected both pre-operatively (90 to 0 days prior to the THA procedure) and post-operatively (270 to 365 days after the THA procedure].

[91] Schalet BD, Rothrock NE, Hays RD, Kazis LE, Cook KF, Rutsohn JP, Cella D. Linking Physical and Mental Health Summary Scores from the Veterans RAND 12-Item Health Survey (VR–12) to the PROMIS® Global Health Scale. J Gen Intern Med. 2015 Jul 16. [Epub ahead of print]

[92] Lyman S, Lee YY, Padget DE. HOOS, JR. a shorter hip outcomes survey. Podium (#413) AAOS 2015 Annual Meeting, Las Vegas, NV.

For hospitals seeking to voluntarily collect and submit PROM data on TKA patients, we will require collection and submission of all of the following for purposes of determining ''successful'' voluntary patient-reported outcome data collection:

- Either VR–12 or PROMIS-Global [collected both pre-operatively (90 to 0 days prior to the TKA procedure) and post-operatively (270 to 365 days after the TKA procedure)], the revised list of risk variables [Table 28, collected only pre-operatively (90 to 0 days prior to the TKA procedure)], and
- Either (A) the KOOS Jr. (7 items total) [collected both pre-operatively (90 to 0 days prior to the TKA procedure) and post-operatively (270 to 365 days after the TKA procedure)] or (B) the original KOOS Stiffness Subscale (2 items), AND the original KOOS Pain Subscale (9 items) and the original KOOS Function, Daily Living Subscale (17 items, for a total of 28 items) [collected both pre-operatively (90 to 0 days prior to the TKA procedure) and post-operatively (270 to 365 days after the TKA procedure)].

Finally, the PROM instrument data will be collected both pre-operatively (90 to 0 days prior to the THA/TKA procedure) and post-operatively (270 to 365 days after the THA/TKA procedure); the risk variables (Table 28) will be collected only pre-operatively (90 to 0 days prior to the THA/TKA procedure). The HOOS/KOOS domain of Quality of Life will be captured by the validated generic instruments (VR–12 or PROMIS-Global); the HOOS/KOOS domain of Function, Sports and Recreational Activities includes questions regarding activities (for example, running) that THA/TKA patients are commonly advised to restrict or avoid after surgery and, as such, is less applicable to this patient population.

*Comment:* A few commenters raised concerns with the HOOS and KOOS instruments, stating that summary scores are not available and the data may not be usable by clinicians. These commenters recommended CMS use generic PROM instruments in place of the HOOS and KOOS, specifically recommending the PROMIS Physical Function Scale, Activity Measure for Post-Acute Care (AM–PAC) Basic Mobility Scale, and OA-Function and Disability Computer Adaptive Tests. In addition, they recommended CMS consider instruments that utilize item response theory (IRT) to develop calibrated item banks to measure physical function and mobility.

*Response:* We appreciate the commenters' concerns about the HOOS/KOOS instruments and have changed the PROM instruments to be submitted as part of the voluntary PRO data collection. Please see our preceding response to other comments for details about the revised PROM instruments for submission that we will be finalizing. The new HOOS/KOOS Jr. instruments provide a single summary score that is strongly correlated with pain and function. In addition, each of the HOOS/KOOS subscales yields its own score. These data, combined with input from this public comment, will be used to develop the THA/TKA PRO–PM. During development of the THA/TKA PRO–PM, we will work with patients, clinicians and technical experts to produce a final measure that provides meaningful information on patients' function and symptoms following elective primary THA/TKA. We also appreciate the commenters' recommendation to use the PROMIS Physical Function Scale, AM–PAC Basic Mobility Scale, and OA-Function and Disability Computer Adaptive Tests for the voluntary PRO data collection. The Technical Expert Panel convened by our measure development contractor discussed the PROMIS Physical Function Scale but favored selection of a combination of joint-specific and generic PROM instruments to capture the domains of pain and function most relevant to patients and clinicians. The Technical Expert Panel also endorsed the use of item response theory with computer adaptive testing (CAT), specifically in reference to non-THA/TKA PROMs developed by NIH, such as the PROMIS® Computer Adaptive Test (*http://www.nihpromis.org/software/demonstration*), as a means to reduce the number of questions while still obtaining meaningful outcome information. However, the Technical Expert Panel acknowledged that CAT instruments are relatively new and still under-developed for use in performance measurement for THA/TKA patient outcomes and require specific software and/or hardware to collect the data. In order to minimize provider as well as patient burden, we have reduced the number of data elements to be submitted for the voluntary PRO data collection and have chosen to avoid proprietary instruments, and at this time chosen to delay using instruments that require specific technology to complete collection. We will continue to review the selection of PROM instruments as the technology and science advances for its ease of use and degree of burden on hospitals.

*Comment:* A commenter suggested that CMS assess the patient-acceptable symptom state (''the highest level of symptom beyond which patients consider themselves well'') and minimum clinically important change (''the smallest change in measurement that signifies an important improvement'') [93] in addition to the proposed PRO data elements.

*Response:* These options were discussed with our contractor's Technical Expert Panel, and, based upon the Technical Expert Panel's aim to utilize the most parsimonious list of required data elements possible and our goal to minimize the burden for hospitals, we decided to delay collecting additional data for this model.

*Comment:* A commenter recommended that CMS publish, as part of the final rule, specific operational definitions of all risk variables, such as quantified spinal pain and knee extensor strength, in order to allow facilities to educate staff prior to data collection.

*Response:* We agree that hospitals cannot be expected to collect meaningful clinical data for risk adjustment without clear, reliable specifications. Please refer to Table 28 that lists the revised list of risk variables required for successful voluntary patient-reported outcome data collection. These variables will be accompanied by one or more unique patient identifier(s) as necessary to enable matching of the PRO data with administrative claims data.

[93] Kvien TK, Heiberg T, Hagen KB. Minimal clinically important improvement/difference (MCII/MCID) and patient acceptable symptom state (PASS): what do these concepts mean? Ann Rheum Dis. 2007 Nov; 66(Suppl 3): iii40–iii41. doi: 10.1136/ard.2007.079798.

TABLE 28—SUMMARY OF PROPOSED AND FINALIZED LIMITED RISK VARIABLE AND PATIENT-REPORTED OUTCOME DATA ELEMENTS TO BE SUBMITTED FOR SUCCESSFUL PARTICIPATION IN VOLUNTARY PATIENT-REPORTED OUTCOMES DATA COLLECTION

| Proposed voluntary PRO * and risk variable data elements | Finalized PRO and risk variable data elements | Definition of finalized PRO and risk variable data elements | Timing of collection |
|---|---|---|---|
| Age | N/A | (Will be captured by linking to claims data). | N/A. |
| Date of Birth ** | Date of Birth | (MM/DD/YYYY) | −90 to 0 days prior to and 270 to 365 days after THA/TKA procedure (to be used for linking to claims data). |
| Gender | N/A | (Will be captured by linking to claims data). | N/A. |
| Race and Ethnicity ** | Race and Ethnicity | Race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White. | −90 to 0 days prior to THA/TKA procedure. |
| | | Ethnicity: Hispanic or Latino, Not Hispanic or Latino. | |
| THA or TKA procedure | N/A | (Will be captured as possible by linking to claims data). | N/A. |
| Date of admission to anchor hospitalization **. | Date of admission to anchor hospitalization. | (MM/DD/YYYY) | 270 to 365 days after THA/TKA procedure (to be used for linking to claims data). |
| Date of discharge from anchor hospitalization. | N/A | (Will be captured as possible by linking to claims data). | N/A. |
| Date of eligible THA/TKA procedure **. | Date of eligible THA/TKA procedure. | (MM/DD/YYYY) | 270 to 365 days after THA/TKA procedure (to be used for linking to claims data). |
| Medicare Health Insurance Claim Number **. | Unique Identifier | Medicare Health Insurance Claim Number. | −90 to 0 days prior to and 270 to 365 days after THA/TKA procedure (to be used for linking to claims data). |
| PROMIS Global (all items) | Generic PROM Instrument for THA and TKA Procedures. | VR–12 OR PROMIS-Global | −90 to 0 days prior to and 270 to 365 days after THA/TKA procedure. |
| VR–12 (all items.) | Generic PROM Instrument for THA and TKA Procedures. | VR–12 OR PROMIS-Global | −90 to 0 days prior to and 270 to 365 days after THA/TKA procedure. |
| For TKA patients Knee injury and Osteoarthritis Outcome Score (*KOOS*[75]) (all items). | Knee-Specific PROM Instrument for TKA Procedures. | KOOS Jr. Only OR KOOS Stiffness Subscale AND KOOS Pain Subscale AND KOOS Function, Daily Living Subscale. | −90 to 0 days prior to and 270 to 365 days after TKA procedure. |
| For THA patients Hip disability and Osteoarthritis Outcome Score (*HOOS*[76]) (all items). | Hip-Specific PROM Instrument for THA Procedures. | HOOS Jr. Only OR HOOS Pain Subscale AND HOOS Function, Daily Living Subscale. | −90 to 0 days prior to and 270 to 365 days after THA procedure. |
| Body Mass Index ** | Body Mass Index (or height in cm and weight in kg). | Body Mass Index (or height in cm and weight in kg). | −90 to 0 days prior to THA/TKA procedure. |
| Presence of live-in home support, including spouse. | N/A | (Will be captured by linking to claims data). | N/A. |
| Use of chronic (≥90 day) narcotics **. | Pre-operative use of narcotics | Provider-reported yes/no | −90 to 0 days prior to THA/TKA procedure. |
| American Society of Anesthesiologists (ASA) physical status classification. | N/A | N/A | N/A. |
| Charnley Classification | N/A | N/A | N/A. |
| Presence of retained hardware | N/A | (Will be captured by linking to claims data). | N/A. |
| Total painful joint count[94] ** | Patient-Reported Pain in Non-operative Lower Extremity Joint. | "What amount of pain have you experienced in the last week in your other knee/hip?" (none, mild, moderate, severe, extreme).[95] | −90 to 0 days prior to THA/TKA procedure. |
| Quantified spinal pain ** | Patient-Reported Back Pain (Oswestry Index question). | "My BACK PAIN at the moment is" (none, very mild, moderate, fairly severe, very severe, worst imaginable).[96] [97] | −90 to 0 days prior to THA/TKA procedure. |
| Joint range of motion in degrees (specify hip or knee). | N/A | N/A | N/A. |
| Use of gait aides | N/A | N/A | N/A. |
| For THA patients abductor muscles strength. | N/A | N/A | N/A. |

TABLE 28—SUMMARY OF PROPOSED AND FINALIZED LIMITED RISK VARIABLE AND PATIENT-REPORTED OUTCOME DATA ELEMENTS TO BE SUBMITTED FOR SUCCESSFUL PARTICIPATION IN VOLUNTARY PATIENT-REPORTED OUTCOMES DATA COLLECTION—Continued

| Proposed voluntary PRO * and risk variable data elements | Finalized PRO and risk variable data elements | Definition of finalized PRO and risk variable data elements | Timing of collection |
|---|---|---|---|
| For THA patients presence of Trendelenberg gait. | N/A | N/A | N/A. |
| For THA patients history of congenital hip dysplasia or other congenital hip disease. | N/A | (Will be captured as possible by linking to claims data). | N/A. |
| For THA patients presence of angular, translational, or rotational deformities of the proximal femur (in degrees). | N/A | (Will be captured as possible by linking to claims data). | N/A. |
| For TKA patients anatomic angle (femoro-tibial angle) in degrees with varus/valgus. | N/A | N/A | N/A. |
| For TKA patients knee extensor strength. | N/A | N/A | N/A. |
| Single Item Health Literacy Screening (SILS2) questionnaire.** | Patient-Reported Health Literacy | ''How comfortable are you filling out medical forms by yourself?'' (extremely, quite a bit, somewhat, a little bit, or not at all).[98] | −90 to 0 days prior to THA/TKA procedure. |

* PRO: Patient-reported outcome survey instrument (see National Quality Forum. Patient reported outcomes (PROs) in Performance Measurement. January 10, 2013. Available at: *http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx*.
** Risk variable data element.

*Final Decision:* After consideration of the public comments we received, and in response to many recommendations from the public commenters, we are finalizing fewer THA/TKA voluntary PRO data submission variables summarized in Table 28 for purposes of ''successful'' voluntary patient-reported outcome data collection. We based our decision to simplify the list of PROM instruments on the numerous public comments recommending simplification of list to be the least burdensome. While we appreciate the many suggestions for other PROM instruments and to use established joint replacement databases and PRO-based measures, we note that many of the suggestions included proprietary instruments, databases and measures. As discussed throughout our responses, when developing measures, we seek to balance requests from the public, the needs of the hospitals, the recommendations from the Technical Expert Panel convened by our measure development contractor regarding identification of the most efficacious and least burdensome PROM instruments for the hospitals, and finally financial cost. For these reasons, we believe that finalizing the PROM instruments listed in Table 28 is the most prudent way to address the concerns voiced by the majority of the public commenters to simplify the list of PROM instruments while also keeping financial burden in mind. Finally, we refer to section III.D.3.a.(9) of this final rule, Requirements for ''Successful'' Submission of THA/TKA Voluntary Data, for an explanation of the requirements that must be met in order to successfully submit THA/TKA PRO data on a voluntary basis and be eligible for a reconciliation payment.

(3) Cohort

In the proposed rule (80 FR 41286), we stated that the measure cohort(s) includes Medicare FFS beneficiaries, aged 65 years or older, admitted to non-federal acute care hospitals for elective primary THA or TKA. We also indicated that we would exclude from the cohort patients with fractures and mechanical complications or those undergoing revision procedures. We stated again that THA and TKA patient-reported outcomes will be assessed separately but may be combined into a single composite measure for reporting.

*Final Decision:* We did not receive public comments on the cohort proposed for the THA/TKA voluntary data submission. We are finalizing the cohort as proposed.

(4) Inclusion and Exclusion Criteria

In the proposed rule (80 FR 41286), we stated that the measure cohort inclusion criteria are all patients undergoing elective primary THA/TKA procedures. Exclusion criteria will consist of patients undergoing non-elective procedures (that is, patients with fractures resulting in THA/TKA), as it is unfeasible to routinely capture pre-operative patient-reported assessments in these patients; patients with mechanical complications of prior hip and knee joint procedures and those undergoing revision THA/TKA will also be excluded, as their patient-reported outcomes may be influenced by prior care experiences and therefore may not adequately represent care quality of the hospital performing the revision procedure.

*Final Decision:* We did not receive public comments on the inclusion or exclusion criteria for the THA/TKA voluntary data submission. We are finalizing the inclusion or exclusion criteria as proposed.

(5) Outcome

In the proposed rule (80 FR 41286), we stated that the measure will assess change between pre- and post-operative

[94] Wallace LS, Rogers ES, Roskos SE, Holiday DB, and Weiss BD. BRIEF REPORT: Screening Items to Identify Patients with Limited Health Literacy Skills. J Gen Intern Med. 2006;21(8):874–7.

[95] Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: The need for a musculoskeletal comorbidity index. J Bone Joint Surg Am. 2013 Oct 16;95(20):1833–7.

[96] Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940–52.

[97] Ayers DC, Li W, Oatis C, Rosal MC, Franklin PD. Patient-reported outcomes after total knee replacement vary on the basis of preoperative coexisting disease in the lumbar spine and other nonoperatively treated joints: The need for *a musculoskeletal comorbidity index*. J Bone Joint Surg Am. 2013 Oct 16;95(20):1833–7. doi: 10.2106/JBJS.L.01007.

[98] Wallace LS, Rogers ES, Roskos SE, Holiday DB, and Weiss BD. BRIEF REPORT: Screening Items to Identify Patients with Limited Health Literacy Skills. J Gen Intern Med. 2006;21(8):874–7.

patient-reported outcomes for THA and TKA separately or as a composite measure for both procedures. We also stated that the measure will use one or more of the following patient-reported outcome instruments (or validated subscales or abbreviated versions of these instruments) to calculate the measure score: The Patient Reported Outcomes Measurement Information Systems (PROMIS)-Global or the Veterans Rand 12 Item Health Survey (VR–12), and the Hip dysfunction and Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) instruments to measure pre- and postoperative improvement or both. These candidate instruments were selected by a Technical Expert Panel convened by our measure development contractor based upon their meaningfulness to patients and clinicians, performance characteristics such as reliability, responsiveness and validity, and their perceived burden to both patients and providers. The pre-operative data collection timeframe will be 90 to 0 days before surgery, and the post-operative data collection timeframe will be 270 to 365 days following surgery. We also indicated that the approach to calculating the improvement or worsening of patient outcomes represented by the pre- and postoperative patient-reported survey results has not yet been determined, but will use one or more surveys to define the improvement or worsening of patient-reported outcomes to reliably identify differences between hospitals of varying performance.

*Final Decision:* We did not receive public comments on the outcomes for the THA/TKA voluntary data submission. We are finalizing the outcomes for the THA/TKA voluntary data as proposed.

(6) Risk-Adjustment (If Applicable)

In the proposed rule (80 FR 41286), we stated that the measure's risk model has yet to be developed. We shared that in order to develop the risk model, final risk variable selection for the risk model will involve empirical testing of candidate risk variables as well as consideration of the feasibility and reliability of each variable. The risk model will account for the hospital level response rate as well as measureable patient-level factors relevant to patient-reported outcomes following elective THA/TKA procedures. We indicated that to the extent feasible, the risk model methodology will adhere to established statistical recommendations.[99]

*Final Decision:* We did not receive public comments on the risk model for the THA/TKA voluntary data submission which has yet to be developed. Please see the following section III.D.3.a.(7) of this final rule for details on how we have reduced the number of voluntary risk variables for collection.

(7) Calculating the Risk-Standardized Rate

In the proposed rule (80 FR 41286) we stated that the approach to reporting this measure(s) has yet to be developed. We outlined in the propose rule that the measure will assess change in patient-reported outcomes between the pre-operative (90 to 0 days prior to the elective primary THA/TKA procedure) and post-operative (270 to 365 days following the elective primary THA/TKA procedure) periods.

We invited public comments on this proposal to seek voluntary participation in submitting data for a Hospital-Level Performance Measure of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty. We also welcomed comments on the appropriateness of this voluntary data collection for this model and the specific data collection requirements (see section III.D.3.a.(9) of the proposed rule) and data elements proposed.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters expressed concern about the amount of data that CMS requested hospitals to report. Some commenters expressed concern that administrative costs of data collection and submission will burden hospitals. Several commenters provided specific risk factors to consider including in the PRO data collection initiative and risk factors to evaluate during future PRO-based measure development. Specifically, a joint statement from multiple surgical specialty societies listed a prioritized list of 11 risk variables: Body Mass Index (BMI), Race/Ethnicity, Smoking Status, Age, Sex, Back Pain, Pain in Non-operative Lower Extremity Joint, Health Risk Status, Depression/Mental Health Status, Chronic or Pre-operative Narcotic Use, and Socioeconomic Status. These variables were also highlighted by other commenters as being important, priority risk variables for consideration for a THA/TKA PRO–PM. Additional specific recommendations included the following potential risk factors: Literacy, marital status, live-in home support, health risk status identified by appropriate comorbid conditions in the Charlson morbidity index or Elixhauser morbidity measure as well as all inpatient and outpatient diagnosis codes for the year prior to the THA/TKA procedure, Charnley classification, retained hardware, total painful joint count, joint range of motion, abductor muscle strength (for THA patients), presence of Trendelenberg gait (for THA patients), history of congenital hip dysplasia or other congenital hip disease (for THA patients), presence of angular, translational, or rotational deformities of proximal femur (in degrees for THA patients), anatomic angle (femero-tibial angle) in degrees with varus/valgus (for TKA patients), knee extensor strength (for TKA patients), baseline pain, function and/or mental/emotional health as assessed by the HOOS/KOOS and VR–12/PROMIS Global, respectively.

*Response:* We note that the submission of patient-reported outcomes data in the CJR model is voluntary and therefore does not impose a mandatory data collection burden on patients or providers. Nevertheless, it is our goal to minimize any additional data collection beyond the PROM surveys, if possible. We considered ease of collection while developing the list of proposed data for collection. Specifically, we considered the estimate of time and effort by the patient and provider to collect data beyond the additional burden of de novo collection of the proposed PROM surveys. If a variable creates a data collection burden to patients, surgeons, hospitals, or the healthcare system, the value of including the variable in the risk model should outweigh the burden.

We appreciate commenter's recommendations regarding specific risk variables for collection. We note the commenter's input that several of these variables can be feasibly collected by self-report and will consider this information when finalizing the data elements for collection.

We appreciate the public comments that the proposed list of current required risk variable data elements for the voluntary PRO data collection is too burdensome. Based upon multiple commenters supporting the risk

[99] Ash AS, Fiengerg SE, Louis TA, Normand ST, Stukel TA, Utts J. STATISTICAL ISSUES IN ASSESSING HOSPITAL PERFORMANCE, Commissioned by the Committee of Presidents of Statistical Societies. Original report submitted to CMS on November 28, 2011, Revised on January 27, 2012. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf.* Accessed on April 15, 2015.

variables prioritized in a joint statement from multiple surgical specialty societies, we have used their list to narrow the risk variable data to be collected in the THA/TKA voluntary data. We believe that several of the specified variables can be adequately captured using administrative claims data (Smoking Status, Age, Sex, Health Risk Status, and Socioeconomic Status, using patient- or community-level factors identifiable by patient zip code), and others (Depression/Mental Health Status) can be captured using the generic PROM instruments (VR–12/PROMIS Global). Therefore, we have removed risk variables not highlighted in the joint statement from multiple surgical specialty societies, as well as, risk variables captured by claims data or by the specified PROM instruments from the voluntary PRO data collection. This leaves eleven risk variables that will be collected, along with the PRO instruments as previously detailed, within −90 to 0 days prior to the THA/TKA procedure for successful completion of the voluntary PRO data collection. These eleven risk variables are defined in Table 28.

We will request that all PRO and risk variable data be submitted through a secure file transfer mechanism using a file template. Hospitals will be able to populate the file template according to their own data collection method and format. CMS will plan to augment the risk model development for the future PRO-based measure with administrative claims, enabling many of the proposed risk variables not selected for voluntary collection to be captured without additional data collection burden. The proposed risk variables for which administrative codes or claims data are available will be considered for possible inclusion in the future PRO-based measure risk model. These individual codes will be considered in addition to the publicly available CMS hierarchical condition categories (CCs) that group the more than 15,000 ICD–9 codes into clinically coherent CCs.[100] Consistent with existing claims-based measures, candidate claims-based risk-adjustment variables will be obtained from inpatient, outpatient, and physician Medicare administrative claims data extending 12 months prior to, and including, the index THA/TKA admission.[101] [102]

*Final Decision:* After consideration of the public comments we received, we are finalizing the Hospital-Level Performance Measure of Patient-Reported Outcomes following Elective Primary Total Hip and/or Knee Arthroplasty cohort, inclusion and exclusion criteria as proposed. In response to our request for comment on the data elements to be collected, we are finalizing the shortened list of PROM instrument elements, and eleven risk variables listed in Table 28.

(8) Performance Period

In Table 16 of the proposed rule (80 FR 41286 through 41288), we proposed defining performance periods for each year of the model (see Table 29 of this final rule). A performance period for the voluntary THA/TKA data submission, are those timeframes in which an anchor hospital admission occurs for eligible THA/TKA voluntary data submission procedure. For the first year of the CJR model, hospitals voluntarily submitting data will only be requested to submit data for a 3-month period. The 3-month period for THA/TKA voluntary data reporting was identified due to data processing and coordination of other proposed timelines in this model. We stated that data submitted for the first year would be for cases that fulfill the measure specifications described in section III.D.3.a. of the proposed rule, and would be restricted to the pre-operative data elements on cases performed between April 1, 2016 and June 30, 2016. The proposed timing allows matching of the patient-reported data with relevant administrative claims-based data in order to accurately calculate the percent of eligible elective primary THA/TKA patients for which THA/TKA voluntary data was successfully submitted. The April 1st date acknowledges the measure requirement of the 90-day window prior to surgery during which hospitals can collect pre-operative data. The June 30th end date was selected because it correlates with the THA/TKA Readmissions measure (NQF #1551) performance period end date currently implemented for the HIQR program and the HRRP. Both of these dates provide the greatest feasibility for data collection.

We went on to explain how the THA/TKA voluntary data reporting periods would change based on the year of the model and whether the data submitted was related to pre- or post-operative THA/TKA assessments. Specifically, we stated that for year 2, THA/TKA voluntary data reporting would be 3 months of post-operative data for cases performed between April 1, 2016 and June 30, 2016, and 12 months of pre-operative data for cases performed between July 1, 2016 and June 30, 2017. We completed our explanation of the duration of performance periods by indicating for year 3 and subsequent years of the model, the performance periods for submission of voluntary data will consist of 12-month time periods. We finally noted in our proposal that the proposed performance period enables hospitals to receive incentives for data collection starting in performance year-one, even though complete pre-operative and post-operative data collection requires a minimum 9- through 12-month time period. This 9- through 12-month time period, between the procedure and post-operative data collection, was defined through clinician and stakeholder input and provides for both sufficient elapsed time for maximum clinical benefit of THA/TKA procedures on patient-reported outcomes and accommodates common clinical care patterns in which THA/TKA patients return to their surgeon one year after surgery. We invited public comments on our proposal of defining performance year-one episodes for a participating hospital as an anchor hospital admission for an eligible THA/TKA procedure between April 1, 2016 and June 30, 2016, with subsequent year performance time periods each being 12-month periods and starting every July 1st.

[100] Pope G, Kautter J, Ingber M, *et al.* 2011 Report: Evaluation of CMS–HCC Risk Adjustment Model. Centers for Medicare & Medicaid Services. 2011. Available at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html.*

[101] Suter LG, Zhang W, Parzynski CS, *et al.* 2015 Procedure-Specific Complication Measure Updates and Specifications Report: Report prepared for the Centers for Medicare & Medicaid Services. 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[102] Suter LG, Desai N, Zhang W, *et al.* 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Report prepared for the Centers for Medicare & Medicaid Services. 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

TABLE 29—PROPOSED POTENTIAL PERFORMANCE PERIODS FOR PER- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION *

| Model year | Performance period | Duration of the performance period | Patient population eligible for THA/TKA voluntary data submission | Requirements for successful THA/TKA voluntary data submission ** |
|---|---|---|---|---|
| 2016 ..... | April 1, 2016 through June 30, 2016*. | 3 months ** ..... | All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016. | Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016. |
| 2017 ..... | April 1, 2016 through June 30, 2016. | 15 months ..... | All patients undergoing elective primary THA/TKA procedures performed between April 1, 2016 and June 30, 2016. | Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between April 1, 2016 and June 30, 2016. |
| 2017 ..... | July 1, 2016 through June 30, 2017. | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017 | Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017. | |
| 2018 ..... | July 1, 2016 through June 30, 2017. | 24 months ..... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and June 30, 2017. | Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2016 and June 30, 2017. |
| 2018 ..... | July 1, 2017 through June 30, 2018. | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018 | Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018. | |
| 2019 ..... | July 1, 2017 through June 30, 2018. | 24 months ..... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018. | Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2017 and June 30, 2018 |
| 2019 ..... | July 1, 2018 through June 30, 2019. | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019 | Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019.. | |
| 2020 ..... | July 1, 2018 through June 30, 2019. | 24 months ..... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019. | Submit POST-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2018 and June 30, 2019. |
| 2020 ..... | July 1, 2019 through June 30, 2020. | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020 | Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% of procedures performed between July 1, 2019 and June 30, 2020. | |

* Due to the new start date of the CJR model of April 1, 2016 (III.C.2.a.) the finalized performance period for the first year of the model will be July 1, 2016 through August 31, 2016 with the duration of performance being 2 months. See Table 30 in section III.D.3.a.(9) of this final rule response to comments.

** Requirements for determining successful submission of THA/TKA voluntary data are located in section III.D.3.a.(9). of the proposed rule.

We did not receive comments on the proposed THA/TKA voluntary data submission Performance Period in Table 16 of the proposed rule or for Table 29 of this final rule, and will be finalizing the THA/TKA voluntary PRO and limited risk variable data submission Performance Period as proposed with the exception of the performance periods for the first year of the model (that is, 2016). We note in section III.C.2.a. of this final rule that the date of implementation will be delayed until April 1, 2016. Previously, we had proposed for 2016 the data collection periods of April 1, 2016 and June 30, 2016. Due to the delay in the implementation date from January 1, 2016 to April 1, 2016, we similarly implement a three month delay for the THA/TKA voluntary PRO and risk variable data submission Performance Period, with the result that we will collect only 2 months of data in 2016 from July 1, 2016 through August 31, 2016. The finalized THA/TKA voluntary PRO and limited risk variable data submission Performance Periods are provided in Table 30 of this final rule.

(9) Requirements for ''Successful'' Submission of THA/TKA Voluntary Data

In proposed rule (80 FR 41286), we stated that in order for CMS to assess if participant hospitals are eligible for reconciliation payment after receiving the THA/TKA voluntary data, requirements to determine if the submitted data would inform measure development had been identified (80 FR 41288 through 41289). We stated our belief that the following criteria should be used to determine if a participant hospital has successfully submitted

THA/TKA voluntary data. We noted that successful THA/TKA voluntary data submission, as stated briefly in section III.C.5.b.(5)(b) (80 FR 41240) and section III.D.3.a.(9) (80 FR 41288) of the proposed rule, required completion of all of the following:

- Submission of the data elements listed in section III.D.3.a.(2) of the proposed rule.
- Data elements listed in section III.D.3.a.(2) of the proposed rule must be submitted on at least 80 percent of their eligible elective primary THA/TKA patients (as described in section III.D.3.a.(3) of the proposed rule).
- THA/TKA voluntary data submission must occur within 60 days of the end of the most recent data collection period.

We proposed that in order to fulfill THA/TKA voluntary data collection criteria for performance year-one, only pre-operative data collection and submission on at least 80 percent of eligible elective primary THA/TKA patients would be required. We further explained that to successfully submit THA/TKA voluntary data for performance years 2 through 5, hospitals would have to submit both pre-operative and post-operative patient reported outcome data on at least 80 percent of eligible elective primary THA/TKA patients. A potential example of the performance periods for which we would like to have THA/TKA voluntary data submitted by participant hospitals were summarized in section III.D.3.a. of the proposed rule.

Table 16 of the proposed rule (80 FR 41287 through 41288) summarized the performance periods for pre-operative and post-operative THA/TKA voluntary data. We also proposed that hospitals volunteering to submit THA/TKA data would be required to submit pre-operative data on all eligible patients and post-operative data elements only on those patients at least 366 days out from surgery. Therefore, hospitals would not be expected to collect and submit post-operative THA/TKA voluntary data on patients who are fewer than 366 days from the date of surgery.

We also stated that a THA/TKA eligible patient is described in section III.D.3.a.(3) of the proposed rule, and noted that this description is important since these patients were those for which we proposed to seek submission of voluntary data. We also selected the requirement of submitting 80 percent of eligible elective primary THA/TKA patients' data because this volume of cases would result in a high probability that we would have a national sample of THA/TKA patient data representative of each hospital's patient case mix. We stated that having 80 percent of the eligible elective primary THA/TKA patients would enable an accurate and reliable assessment of patient-reported outcomes for use in measure development. We noted that data used for outcome measure development must adequately represent the population that is anticipated to be measured, and in this case that population would be those experiencing elective primary THA/TKA inpatient surgical procedures. Data that more accurately reflects the patient outcomes and case mix of the population to be measured would allow, during measure development, a more scientifically accurate and reliable measure. We stated our belief that having 80 percent of eligible elective primary THA/TKA recipient data would result in a more reliable measure that is better able to assess hospital performance than a measure created from a less representative patient sample. Furthermore, we considered setting the requirement at 100 percent of the eligible elective primary THA/TKA patients, but concluded that a requirement of 100 percent data collection may not be feasible for all hospitals or may be excessively burdensome to achieve. Therefore we proposed to set the requirement at 80 percent of the eligible elective primary THA/TKA patients. We believed acquisition of 80 percent of the eligible elective primary THA/TKA patients would provide representative data for measure development while decreasing patient, provider and hospital burden. We sought public comment of these requirements to determine successful voluntary submission of THA/TKA data. We also sought public comment specifically on the requirement for data on 80 percent of the eligible elective primary THA/TKA patients.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters expressed concern over the proposed successful criterion of 80 percent; some noted they had successfully achieved PROM response rates over 80 percent but still expressed concern that hospitals would be able to meet this criterion. Several commenters recommended that CMS wait to establish the successful criterion until CMS has further experience with the measure and sufficient data to determine an appropriate number. Several commenters recommended CMS lower the successful criterion from 80 percent in Year 1 (A commenter specifically noted 50 percent), and then phase-in higher successful criterion over time. A commenter recommended lowering the successful criterion because the proposed number would add a substantial added cost for active surveillance to achieve 80 percent. A commenter recommended a 40 percent successful criterion because an 80 percent successful criterion—(1) Might prohibit hospitals from participating in the voluntary data reporting effort; and (2) might prohibit otherwise compliant hospitals from receiving additional reconciliation payments through discounted target rates. Another commenter recommended that the 2 percent discount should not be lowered to pay for the voluntary data submission, but instead the 80 percent successful criterion should be lowered. A few commenters recommended CMS pay for every case that has data submitted. Some commenters recommended that CMS increase the successful criterion. Other commenters urged CMS to ensure that the collected data are not biased by high-performing providers or selective reporting of cases that have positive outcomes.

*Response:* We thank the commenters for their input on the proposed 80 percent criterion that defines successful voluntary data submission of voluntary patient-reported outcome data (80 FR 41288). We refer reviewers to section III.C.5. of this final rule for the finalized policies on how hospital performance on finalized measures and successful submission of THA/TKA voluntary data will be assessed for purposes of reconciliation payment eligibility.

We appreciate the commenter's suggestion to increase the successful criterion based upon the concern that lowering the successful criterion (that is, the patient-reported outcome instrument response and risk variable submission rates required for successful participation) may produce biased data that are not generalizable to all patients undergoing elective primary THA/TKA procedures at a given hospital. To assess the amount of data bias, the collected and submitted patient-reported outcome and risk variable data will be matched to administrative claims data, which will allow CMS to determine the proportion of a hospital's patients for which the hospitals collected and submitted patient-reported outcome and risk variable data. In addition, it will allow CMS to determine how representative this sampling of patients is of all of the hospital's eligible THA/TKA patients, by comparing the number and type of comorbid conditions, sociodemographic factors, and post-discharge outcome (for example, complication and readmission) rates. This information will be factored into any measure development work that

utilizes the voluntary patient-reported outcome data.

While there are a few commenters supporting the feasibility of pre- and post-operative patient-reported outcome instrument response rates exceeding 80 percent for elective THA/TKA procedures, we understand that many hospitals may not be able to meet this criterion as proposed in the first year of the CJR model. Therefore, based on public comments we are finalizing a lower criterion for the ''successful'' voluntary patient-reported outcome and limited risk variable data collection for year 1, which will entail each participating hospital submitting the required pre- and post-operative data elements (see Table 28 for the final list of voluntary patient-reported outcomes and limited risk variable data elements) on either of the following

- 50 percent of eligible procedures during the data collection period; or
- A total of 50 eligible procedures during the data collection period.

This will allow hospitals the opportunity to actively engage in data collection but, consistent with the experiences reported by several commenters, acknowledges the realities that such systematic data collection efforts require time to implement. It also responds to commenters' suggestion for CMMI to pursue a ''phase-in'' approach to collecting PRO data. As previously noted, CMS will actively evaluate the submitted data for evidence of reporting bias.

Eligible patients (henceforth for purposes of this discussion, patients will be described as procedures) are described in section III.D.3.a. of the proposed rule (80 FR 41286). The post-operative data collected in year 2 will correspond to the pre-operative data collected in year 1 and, similarly, for years 3 through 5. That is, participant hospitals will collect and submit post-operative data for the same cases for which the hospital submitted pre-operative data in the preceding year.

Based upon commenters' input to reduce the successful criterion, including a recommendation specifically to reduce the successful criterion to 50 percent, we believe a '50 percent or 50 eligible procedures' successful criterion in year 1 provides hospitals with flexibility to minimize the data collection burden; using a 50 percent or 50 eligible procedures successful criterion in year 1 will also allow participant hospitals to submit data regardless of their case volume. A 50 percent or 50 eligible procedures successful criterion in year 1 also allows participant hospitals an opportunity for financial reward for this voluntary initiative. We note having the 50 percent or 50 eligible procedures successful criterion in year 1 in conjunction with a simplified list of PROM instruments and list of risk variables (Table 28) markedly decreases the burden of collecting and submitting the THA/TKA voluntary PRO and limited risk variable data. We believe after the first year of the model, hospitals will become more adept at collecting this data, and the public comments indicate that much higher patient-reported outcome data collection rates are feasible. For example, a commenter shared that its institution reported a reliable 85 percent response rate for its PROM data collection. Therefore, we believe it is reasonable to gradually increase the expected response rates to successfully fulfill the THA/TKA voluntary PRO and limited risk variable data collection in years 2 through 5 of the model, as listed in Table 30. We note that the phase-in approach was suggested by a few public commenters. We agree that phasing in of higher percentage eligible procedures with each year is a more realistic expectation for participating hospitals to meet and a more encouraging manner to enhance the THA/TKA voluntary PRO and limited risk variable data submission.

We anticipate completion of measure development for the future hospital-level THA/TKA PRO–PM during or before year 3 of the model. The measure specifications will be finalized in accordance with our standard measure development process set forth in NQF guidance for outcome measures,[103] CMS Measures Management System (MMS) guidance,[104] and the guidance articulated in the American Heart Association Statement ''Standards for Statistical models Used for Public reporting of Health Outcomes.'' [105] Given the support for the PRO data collection and support for mandatory inclusion of a PRO–PM in this model from several commenters during public comment, we anticipate integrating this new measure as a mandatory measure in the CJR model in years 4 and 5 through future rulemaking. We anticipate that the PRO–PM would be considered similarly in the CJR model to the THA/TKA Complications measure (NQF #1550), with better performing hospitals receiving higher quality scores and therefore higher reconciliation payments. The current quality measure weighting system would be reconfigured to give this PRO–PM equal weighting with the other quality measures included in years 4 and 5 of the model, again through future rulemaking. Hospitals participating in the voluntary PRO data collection in years 1 through 3 would be better prepared for the addition of the hospital-level THA/TKA PRO–PM to the model in years 4 and 5. The anticipated use of this PRO–PM in this model is consistent with stakeholder feedback during public comment strongly encouraging mandatory integration of PRO-based measures into the model. We will also consider adding or removing patient-reported outcome and/or risk variable data elements as indicated by clinical practice and empirical analyses supporting or refuting their utility in performance measurement. For further discussion on the use of PRO–PM measure, see section III.C.5. of this proposed rule.

[103] National Quality Forum. Measure Evaluation Criteria and Guidance. April 2015. Available at: *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx*. Accessed on September 22, 2015.

[104] Measures Management System Overview.2015; *http://www.cms.gov/Medicare/Quality-InitiativesPatient-AssessmentInstruments/MMS/index.html?redirect=/MMS/19_MeasuresManagementSystemBlueprint.asp*. Accessed September 8, 2015.

[105] Krumholz H, Brindis R, Brush J, *et al.* Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council. Endorsed by the American College of Cardiology Foundation. *Circulation*. Jan 24 2006;113(3):456–462.

TABLE 30—FINALIZED PERFORMANCE PERIODS FOR PRE- AND POST-OPERATIVE THA/TKA VOLUNTARY DATA SUBMISSION

| Model year | Performance period | Duration of the performance period | Patient population eligible for THA/TKA voluntary data submission | Requirements for successful THA/TKA voluntary data submission |
|---|---|---|---|---|
| 2016 ..... | July 1, 2016 through August 31, 2016. | 2 months ..... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 and August 31, 2016. | Submit PRE-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 and August 31, 2016. |
| 2017 ..... | July 1, 2016 through August 31, 2016. | 13 months ... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2016 through August 31, 2016. | Submit POST-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 through August 31, 2016. |
| 2017 ..... | September 1, 2016 through June 30, 2017. | ..... | All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 through June 30, 2017. | Submit PRE-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 through June 30, 2017. |
| 2018 ..... | September 1, 2016 through June 30, 2017. | 22 months ... | All patients undergoing elective primary THA/TKA procedures performed between September 1, 2016 and June 30, 2017. | Submit POST-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017. |
| 2018 ..... | July 1, 2017 through June 30, 2018. | | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018. | Submit PRE-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018. |
| 2019 ..... | July 1, 2017 through June 30, 2018. | 24 months ... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2017 and June 30, 2018. | Submit POST-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018. |
| 2019 ..... | July 1, 2018 through June 30, 2019. | ..... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019. | Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019. |
| 2020 ..... | July 1, 2018 through June 30, 2019. | 24 months ... | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2018 and June 30, 2019. | Submit POST-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019. |
| 2020 ..... | July 1, 2019 through June 30, 2020. | | All patients undergoing elective primary THA/TKA procedures performed between July 1, 2019 and June 30, 2020. | Submit PRE-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020. |

*Comment:* A commenter recommended the use of ''Advanced Procurement Technology'' for submission of PRO data and to alleviate burden of data submission by physicians and patients. Specifically, the commenter recommended the use of a cloud-based central server to reduce administrative costs.

*Response:* We note that the future PRO–PM measure will potentially employ multiple platforms for data collection, including electronic health records (EHRs), as well as other data collection mechanisms, but will not be limited to EHRs. We aim to construct a secure data collection system that reduces the amount of data submission burden on hospitals. We encourage hospitals to collect and transfer the PRO data in the most economically efficient mode for individual hospitals.

*Comment:* Several commenters suggested CMS consider a pay-for-reporting approach, which would allow hospitals that successfully submit data to be eligible for savings.

*Response:* We have been careful to identify a way in which to reward hospitals that participated in this initiative, as we understand that this could be a potential added burden, but the composite quality score methodology initiative also becomes a way for hospitals to learn about their patients' outcomes post-primary elective THA/TKA procedures. We believe that section III.C.5.b. in this final rule provides a full discussion of voluntary PRO data collection from a payment perspective.

*Final Decision:* After consideration of the public comments we received, we will not be finalizing the proposed successful criterion on 80 percent of eligible procedures. In response to public comments we are finalizing a modification to the requirements for what will be considered as ''successful'' submission of THA/TKA voluntary PRO data, as noted in Table 30, in conjunction with a simplified list of PROM instruments and list of risk variables (Table 28). We are also finalizing the proposed requirement that the required THA/TKA voluntary PRO data and the limited list of risk variables be submitted to CMS within 60 days of the end of the most recent performance period. We believe requirements for the THA/TKA voluntary PRO data and limited list of risk variables that we are finalizing will markedly decrease the burden of collecting and submitting the THA/TKA voluntary PRO data by participant hospitals. We also believe that reducing the data collection and submission burden will enhance the opportunity for participant hospitals to improve their composite quality score that is being finalized for the CJR model.

We are codifying requirements for successful data submission of THA/TKA patient reported outcomes and limited risk variable data in § 510.400(b).

b. Measure That Captures Shared Decision-Making Related to Elective Primary Total Hip and/or Total Knee Arthroplasty

In the proposed rule (80 FR 41289), we shared our belief that, in addition to the patient-reported functional status outcomes, shared-decision making is an important aspect of care around elective patient-reported outcome procedures such as primary total hip and total knee arthroplasty. We also noted that lower episode expenditures achieved through improved patient-reported outcome efficiency may yield the unintended consequence of a compensatory increase in the number of episodes initiated. We stated that use of shared decision-making prior to episode initiation can serve as an important tool to ensure appropriate care. Though there are no developed measures, we sought feedback on the opportunity to capture quality data related to shared decision-making between patients and providers. Examples of such a measure could include concepts such as a trial of conservative medical therapy prior to elective procedures or broader shared decision-making measures. We invited public comment on whether such a measure concept would be appropriate for the CJR model. If we develop a measure that captures shared decision-making related to elective primary total hip and total knee arthroplasty or both, we would propose through rulemaking or other means to add that measure to the CJR model.

The following is a summary of the comments received and our responses.

*Comment:* Many commenters supported the development and use of measures related to shared decision-making. Most commenters agreed that shared decision-making is critical for the patient-reported outcome when patients are deciding whether or not to undergo elective TKA/THA procedures, and that CMS should promote shared decision-making as part of a way to optimize patient-reported outcomes. A commenter recommended that a shared decision-making measure should be documented within the referral visit by the primary care physician. Another commenter recommended that a shared decision making measure have both a pre- and post-intervention component. A commenter recommended that shared decision-making be required as part of the model. Multiple commenters suggested additional measures that should be paired with shared decision-making measures, including a functional outcome measure, a measure for risk adjustment, a measure for care planning, quality measures that assess clinical excellence, and the pairing of the measure with patient-reported outcome criteria to evaluate patterns of care. Many commenters recommended that shared decision-making measures require or document the use of certified or patient-reported outcome decision aids, though no specific decision aids were suggested. Finally, a number of commenters recommended that CMS use this opportunity to further the research agenda related to shared decision-making and its measurement.

*Response:* We appreciate all of the responses on how we might address shared-decision making from the quality measure perspective. For a detailed discussion of shared decision-making as it relates to beneficiary patient-reported outcomes and experience, please refer to beneficiary patient-reported outcome sections in section III.D.3.a. of this final rule. We agree that shared decision-making is important for patient-reported outcomes, as well as meaningfully measuring shared decision-making. Based on the comments we received, we will consider the future development of measures related to shared decision-making. Should we decide to implement a shared decision-making measure in the future, we will do so through notice-and-comment rulemaking.

c. Future Measures Around Care Planning

In the proposed rule (80 FR 41289), we stated that person-centered shared care plan is an important tool that can help providers across settings collaborate around a customized plan that reflects a patient's goals and offers providers critical information about all of the treatment a beneficiary has received. We shared that health IT solutions are increasingly supporting the exchange of care plan information across settings so that providers and individuals have access to necessary information whenever and wherever it is needed. We also indicated that in the 2015 Edition of certification criteria for health information technology (80 FR 16842), the Office of the National Coordinator for Health Information Technology (ONC) proposed the adoption of a new criterion to ensure health IT can capture, display, and exchange a robust care plan document in accordance with new standards released in the Consolidated Clinical Document Architecture Release 2.1; this proposal has now been finalized (80 FR 62648). While further measure development is needed, we sought comment on the appropriateness of a future quality measure which would assess the use of shared care plans in the care of beneficiaries participating in the CJR model.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters supported the future inclusion of a measure focused on shared care planning in the model, pending further measure development. A commenter noted that a shared care plan measure could help to ensure that hospitals are taking steps to assist patients in understanding the potential tradeoffs associated with surgical interventions. Another commenter focused specifically on the need for advance care planning within a bundled payment model, noting that CMS should seek to require the hospital initiating the episode to conduct advance care planning discussions and offer beneficiaries the opportunity to complete an advance directive. Commenters encouraged CMS to incentivize providers to voluntarily submit data that would support future measure development in this area.

*Response:* While we did not propose to include a measure of care planning activities, we will consider these comments as we explore any future action in the CJR model. Should we decide to implement a measure of care planning activities in the future, we will do so through notice-and-comment rulemaking.

d. Future Measures for Use of Health IT and Health Information Exchange

In the proposed rule (80 FR 41289), we shared our belief that the use of health IT tools is a critical component of effective coordination across settings of care. Under bundled payment models, in which providers across the continuum of care share accountability for the clinical management and total cost of an episode of care, the capacity to share information electronically across disparate provider systems is essential for delivering efficient, safe, high quality care. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*), we believe that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. ONC has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' (available at *https://www.healthit.gov/*

*sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*), which describes barriers to interoperability across the current health IT landscape, the desired future state that will be necessary according to the industry to enable a learning health system, and a suggested path for moving forward. ONC will focus on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Under section 1833(z)(3)(D)(i)(I) of the Act, as amended by section 101(e) of the MACRA, providers participating in qualifying APMs under Medicare will be required to use certified EHR technology beginning in 2019. As this date approaches, we believe it will be important for providers working in these models to demonstrate adoption of health IT.

We shared our belief that use of certified health IT tools and the interoperable exchange of health information is a critical capability for model participants to be able to deliver the high-quality care and effective coordination across settings that will be required to demonstrate success under the model. Moreover, we believe that it will be important to incentivize adoption and use of these enabling technologies among model participants including PAC providers, by linking these activities to participant eligibility to receive reconciliation payments.

While we did not propose to add a measure for certified health IT use for the program's initial performance year, we sought comment on how we might incorporate such a measure beginning in the 2017 performance year. We invited stakeholder comment on the following questions:

- Is successful attestation as part of the EHR Incentive Program for Medicare hospitals in the applicable reporting year the most appropriate quality measure for assessing hospital performance on the use of health IT and interoperable health information in the model?
- Should the model include a performance measure that would be specific to the ability of hospitals to conduct electronic care coordination using certified health IT, for instance, the measure of transitions of care which hospitals currently report on as part of the EHR Incentive Program for Medicare Hospitals?
- What other measures could be used to assess hospital performance on the use of health IT and interoperable health information while minimizing program and provider collection and reporting burden?

We sought public comments on how we might incorporate an electronic measure beginning in the 2017 performance year, and public comments on the questions posed previously in this rule.

We also sought public comment on the appropriateness of quality measures for PAC patients, physicians and facilities that care for THA/TKA surgical procedure patients.

The following is a summary of the comments received and our responses.

*Comment:* While commenters noted the importance of health IT systems and health information exchange to support the care coordination required to succeed under a bundled payment approach, a number of commenters expressed concerns about introducing a measure of health IT utilization or health IT requirements within the model. A commenter suggested that the model should focus on outcomes rather than introducing measures of the care delivery process, such as the use of health IT. Another commenter believed that health IT requirements would restrict the flexibility of model participants to explore different modes of care delivery needed to succeed within the model. Another commenter noted that a measure of health IT use would not be appropriate because hospitals already participate in the EHR Incentive Program, and a similar measure under the program would create a duplicative penalty.

Several commenters noted that hospitals have substantially increased their adoption of health IT systems in recent years, and that participants will need to rely on electronic tools, including EHRs, health information exchange services, and other systems, in order to deliver effective care for beneficiaries under the model. Commenters also noted that many hospitals are seeking to address challenges around electronically exchanging patient information with PAC providers. As these PAC providers were not eligible for the EHR Incentive Programs, many have not yet established health IT systems. However, bundling programs such as the CJR model are likely to further incentivize hospitals to develop strategies to share information with these providers to support care coordination across an episode of care.

*Response:* We appreciate the insights and concerns expressed around utilizing a measure of health IT tied to participation in the EHR Incentive Programs. While we did not propose to include a measure of health IT utilization, we will consider these comments as we assess any future action for the model. As future measures become available, such as measures which focus directly on electronic exchange between all providers participating in a bundle, we will continue to explore whether there are opportunities to address this important aspect of care delivery for model participants. Should we decide to implement a measure of health IT utilization in the future, we will do so through notice-and-comment rulemaking.

*Final Decision:* After seeking comments on shared decision-making, and on future measures around Care Planning and future considerations for use of electronic health records, we thank the public for these comments and will evaluate the suggestions for future consideration.

4. Form, Manner, and Timing of Quality Measure Data Submission

In the proposed rule (80 FR 41289), we stated that it is important to be transparent and to outline the form, manner and timing of quality measure data submission so that accurate measure results are provided to hospitals, and that timely and accurate calculation of measure results are consistently produced to determine annual reconciliation payment.

We proposed that data submission for Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) and Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (or both) be accomplished through the existing HIQR Program processes. Since these measures are administrative claims-based measures, hospitals will not need to submit data. We proposed that the same mechanisms used in the HIQR Program to collect HCAHPS Survey measure (NQF #0166) data also be used in the CJR model (79 FR 50259). For the hospitals that voluntarily submit data for the THA/TKA patient-reported outcome-based performance measure, we anticipated, if it is technically feasible, for data submission processes to be broadly similar to those summarized for the HIQR Program for chart abstracted and administrative claims-based measures. We indicated that we would create a template for hospitals to complete with the THA/TKA voluntary data, provide a secure portal for data submission, and provide education and outreach on how

to use these mechanisms for data collection and where to submit the THA/TKA voluntary data. We also repeated our description of potential processes for voluntary data collection in section III.D.3.a.(2) of the proposed rule, and noted that these were broadly similar to those used by the HIQR Program.

We invited public comment on the proposal to collect quality measure data through mechanisms similar to those used in the HIQR Program.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters requested quarterly releases of measure results for the purposes of continuous quality improvement since they believed that an annual release of measure results would not facilitate effective continuous quality improvement.

*Response:* We acknowledge the request for hospitals to more frequently receive their measure results in order to enhance effective quality improvement. With respect to the measures that we are finalizing for the CJR model, we note that hospitals already receive their measure results on the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) through the HIQR Program on an annual and quarterly basis, respectively (69 FR 49082 and 78 FR 50783). With respect to the THA/TKA Complications measure (NQF #1550), CMS provides hospitals with their confidential preview reports and hospital-specific reports with discharge level information used in the calculation of their measure result around April each year before the results are publicly reported on the *Hospital Compare* Web site (77 FR 53598). We note that the *Hospital Compare* Web site is the vehicle that provides public reporting and within this Web site we indicate that this Web site fulfills section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, which requires the Secretary to establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Prior to the release of data on *Hospital Compare,* hospitals are given the opportunity to review data during a 30-day preview period via the *QualityNet Secure Portal* (*http://www.qualityreportingcenter.com/wp-content/uploads/2015/07/IQR_FY-2017_Hospital-IQR-Program-Reference-Checklist_Tool_7.21.2015_FINAL508.pdf*).

With respect to the HCAHPS Survey measure (NQF #0166), CMS similarly provides hospitals with their confidential preview reports on a quarterly basis, before the results are publicly reported on Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*) (*78 FR 50778*). We believe that the current frequency of sharing measure results data with hospitals is also appropriate for the CJR model and does allow effective quality improvement for the following reasons. First of all, we note that other CMS IPPS quality programs besides the HIQR Program, such as HVBP (77 FR 53579), the HRRP (77 FR 53399), and the Hospital-Acquired Condition Reduction Program (78 FR 50725), similarly use an annual cycle for sharing measure results with hospitals and publicly reporting quality measure performance as we are finalizing for the CJR model. For example, the HIQR Program and the HRRP release annual measure results data to hospitals on their excess readmissions (77 FR 53399). The acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, and ischemic stroke readmission measure results have all shown improvements in hospital performance between 2010 and 2013 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Medicare-Hospital-Quality-Chartbook-2014.pdf*). This strongly suggests that effective continuous quality improvement is possible with annual review of measure results by hospitals. Secondly, because the THA/TKA Complications measure (NQF #1550) uses a 3-year rolling performance period that is 'rolled forward' by 12 months each HIQR Program year, quarterly updates to the 3-year performance period would yield minimal actionable information to hospitals from one quarter to the next, while increasing administrative burden for hospitals to download and review their hospital-specific reports and discharge-level data. We remind readers that the 3-year performance period is used for the THA/TKA Complications measure (NQF #1550) in order to identify a greater number of eligible index admissions for each hospital. Increasing the sample size by using a larger number of index admissions to identify the measure cohort improves the reliability and precision of the estimation of each hospital's results for the THA/TKA Complications measure (NQF #1550), as well as allow for the calculation of measure results that more meaningfully distinguish hospital performance. For these reasons, we do not believe that providing more frequent measure results data to participant hospitals in the CJR model than are already provided to them in the HIQR Program will provide sufficiently new, actionable information to meaningfully enhance their continuous improvement processes.

*Comment:* A commenter recommended that CMS establish the low-volume thresholds for the quality measures prior to the first performance year and exclude low-volume hospitals from the CJR model.

*Response:* As noted in the proposed rule (80 FR 41242), a participant hospital with an insufficient volume of episodes on which to determine performance on an individual measure will be assigned to the 50th percentile so as not to disadvantage a participant hospital based on its low volume because that hospital may in actuality provide high quality of care. Additionally, we proposed that data submission for Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550) be accomplished through the existing HIQR program processes (80 FR 41290). By using existing HIQR program processes we intend to apply the same low-volume case thresholds applied to all claims based measures which is set at 25 cases for public reporting (75 FR 50185 and 76 FR 51609). For the HCAHPS Survey measure (NQF #0166) we have previously indicated in section III.D.2.c. of this final rule that a minimum of 100 cases is required for the measure which is also consistent with the threshold set for HVBP program (76 FR 26502)

*Comment:* A commenter recommended beginning the process of vendor certification as soon as possible with respect to patient-reported outcome data collection. Specifically, the commenter recommended CMS use previously established vendor guidelines such as those governing the data submission process for chart-abstracted measures or electronic clinical quality measures (eCQM).

*Response:* We will consider this recommendation when and if patient-reported outcome data collection is mandatory. The current patient-reported outcome data collection is voluntary, and hospitals can collect the data using whatever mechanisms are available to them.

*Comment:* A few commenters recommended we use a standardized data collection file template with respect to patient-reported outcome data

collection. A commenter recommended creating a file template for data collection in a web-based platform.

*Response:* We plan to create a standardized file template to assist hospitals' data collection and submission efforts for the patient-reported outcome data. We will take the commenter's recommendation to create a web-based data collection template into account when we design the template prior to the start date of the CJR model.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposals as to the form, manner, and timing of data submissions to CMS by participant hospitals for THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) used in the CJR model, the frequency of sharing of measure results with participant hospitals annually, and the proposed performance periods set forth in Table 32. We note that the form, manner, and timing of data submissions to CMS by participant hospitals for THA/TKA Readmissions measure (NQF #1551) is not finalized since the THA/TKA Readmissions measure (NQF #1551) is not being adopted for the CJR model.

5. Display of Quality Measures and Availability of Information for the Public From the CJR Model

In the proposed rule (80 FR 41290), we stated our belief that display of quality data is an important way to educate the public on hospital performance. We have used several methods to report quality data to the public, including posting data on the *Hospital Compare* and *data.medicare.gov* Web sites. We shared that data have been available for viewing on these Web sites and in downloadable databases since 2005, and are well-known mechanisms for providing information to the public. We proposed to post data for measures included in the CJR model for each participant hospital on the *Hospital Compare* Web site in an easily understood format. The proposed applicable time periods for the measures during the CJR model initiative are summarized in Table 17 of the proposed rule (80 FR 41290) and in the following Table 31.

TABLE 31—SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CJR MODEL

| Measure title | Model year | | | | |
|---|---|---|---|---|---|
| | 1st | 2nd | 3rd | 4th | 5th |
| THA/TKA Complication * ..... | April 1, 2013–March 31, 2016. | April 1, 2014–March 31, 2017. | April 1, 2015–March 31, 2018. | April 1, 2016–March 31, 2019. | April 1, 2017–March 31, 2020. |
| THA/TKA ** Readmission ..... | July 1, 2013–June 30, 2016. | July 1, 2014–June 30, 2017. | July 1, 2015–June 30, 2018. | July 1, 2016–June 30, 2020. | July 1, 2017–June 30, 2016. |
| HCAHPS *** ..... | July 1, 2015–June 30, 2016. | July 1, 2016–June 30, 2017. | July 1, 2017–June 30, 2018. | July 1, 2018–June 30, 2019. | July 1, 2019–June 30, 2020. |

* Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

** Hospital-Level Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).

*** HCAHPS Survey measure (NQF #0166).

We stated that the proposed time periods for the THA/TKA Complications measure (NQF #1550), and the THA/TKA Readmissions measure (NQF #1551) are consistent with HIQR Program performance periods for July 2017 public reporting. The HCAHPS Survey measure (NQF #0166) results performance periods as previously stated in section III.D.2.c. of this final rule would not align with the HIQR program. We also stated our belief that the public is familiar with the proposed measures, which have been publicly reported in past releases of Hospital Compare as part of the HIQR Program. Finally, we clarified in the propose rule our intent to minimize confusion and facilitate access to the data on the measures included in the CJR model by proposing to post the data on each participant hospital's performance on each of the 3 proposed quality measures in a downloadable format in a section of the *Hospital Compare* and *data.medicare.gov* Web sites specific to the CJR model, similar to what is done for the Hospital Readmissions Reduction Program and the Hospital-Acquired Conditions Reduction Program. We also proposed to post data on whether or not each participant hospital met the proposed threshold (section III.C.5.b. of the proposed rule) for receiving a reconciliation payment in the same downloadable database; we note that section III.C.5. of this final rule provides a detailed discussion on the final decision for indicating which hospitals are eligible for a reconciliation payment.

In addition, we also stated our belief that information about functional status both pre- and post-operatively is important for hip and knee replacements. We are developing a functional status measure that we believe will provide this needed information. The measure, Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (see section III.D.3. of the proposed rule for a detailed description), requires comprehensive testing before it can be used in a CMS program. As part of the effort to collect data on functional status voluntarily from hospitals, we proposed that hospitals that voluntarily submit data for this measure be acknowledged through the use of a symbol on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*). The data submitted voluntarily for the functional status measure would not be publicly reported along with the other measures in the program.

We also provide clarification for the performance periods proposed for years 4 and 5 in Table 17 (80 FR 41290) in the proposed rule, and in Table 31 of this final rule, for the THA/TKA Readmissions measure (NQF #1551). In Table 17 of the proposed rule we had indicated a year 4 performance period of: July 1, 2016 through June 30, 2020 and for year 5 July 1, 2017 through June 30, 2016. We note that these proposed time frames are not consistent with prior proposals (80 FR 41290) and would like to clarify that the correct proposed performance periods for the THA/TKA Readmissions measure (NQF #1551) for year 4 is: July 1, 2016 through June 20, 2019; and for year 5: July 1, 2017 through June 30, 2020. We also note that the THA/TKA Readmissions measure (NQF #1550) has not been finalized for this model.

We invited public comments on these proposals to post data for mandatorily required measures on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) and to acknowledge hospitals that voluntarily submit data for the functional status measure with an icon on the *Hospital Compare* Web site.

The following is a summary of the comments received and our responses.

*Comment:* A few commenters supported the public reporting of measure results.

*Response:* We appreciate the support of our proposal to publicly report measure results implemented in the CJR model.

*Comment:* A commenter recommended that CMS give participant hospitals a year-long preview of measure performance prior to the public release of data. Another suggested that CMS delay public reporting of performance data for at least one year into the CJR model while allowing participant hospitals to preview their measure results during that time.

*Response:* We appreciate these two comments, and note our belief that the availability of quality data to the public is an important way to educate the public, including patients, consumers, and their family members and care givers, on hospital performance and that not publicly reporting such quality data as soon as they are available would not be consistent with our policy to be transparent with CMS quality and payment programs. Further, the finalized measures are currently used in the HIQR Program, and hospital performance information is publicly reported for this program on the Hospital Compare Web site. We refer reviewers to section III.C.5.b. of this final rule for further discussion of pay-for-reporting during the first year of the model from a payment perspective.

*Comment:* A few commenters requested clarification as to whether CMS intends to provide PRO data preview reports for participating hospitals.

*Response:* To provide further clarification regarding the release of quality measure results information to hospitals prior to public reporting on Hospital Compare Web site, we stated in the proposed rule (80 FR 41290) that we would use existing CMS hospital public reporting processes as in the HIQR Program. We also emphasized in the proposed rules the importance of providing accurate measure results to hospitals and the timely and accurate calculation of measure results that are consistently produced to determine annual reconciliation payments (80 FR 41290). As in the HIQR Program for outcome measures, we will deliver confidential reports and accompanying confidential discharge level information, as applicable to the measure, to participant hospitals on an annual basis. These reports will contain hospital-specific information on the THA/TKA Complications measure (NQF #1550), the HCAHPS Survey measure (NQF #0166), and whether a hospital has successfully submitted the voluntary patient-reported outcome data. The reports will be delivered in participant hospitals' secure QualityNet accounts prior to the information being made available to the public.

We will provide participant hospitals a period of 30 days to review and submit corrections to calculations of measure results and determinations of successful patient-reported outcome data submission using a process that is similar to the process currently used for posting results on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) in programs such as the HIQR, HVBP, HRRP programs and the Hospital-Acquired Condition Reduction Program. Our intent in providing this information is two-fold—(1) To facilitate hospitals' verification of their measure results calculations; and (2) to facilitate hospitals' quality improvement efforts with respect to the care provided to LEJR patients. More specifically, this 30-day period will begin when the participant hospitals' confidential reports and accompanying discharge-level information are posted to their QualityNet accounts. This time period will enable us to evaluate correction requests in a timely manner in order to provide accurately calculated measure results for the determination of annual reconciliation payments. We believe that this review and corrections process will ensure that hospitals are able to fully and fairly review their measure results as they will be used in the CJR model and publicly reported on the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*).

We note that with respect to the claims based THA/TKA Complications measure (NQF #1550), the review and correction process will not include submitting additional corrections related to the underlying claims data we used to calculate the measure result, nor adding new claims to the data extract we used to calculate the measure result. This is because it is necessary to take a static ''snapshot'' of the claims in order to perform the calculations. For purposes of the CJR model, we would calculate the THA/TKA Complications measure (NQF #1550) result using a static snapshot (that is, data extract) taken at the conclusion of the 90-day period following the last date of discharge used in the applicable performance period. This is consistent with our policy for all claims-based measures used in the HIQR, HVBP, HRRP programs, and the Hospital-Acquired Condition Reduction Program (for example, see 77 FR 53399 through 53401 as this policy is applied for HRRP and 78 FR 50725 through 50727 as this policy is applied in the Hospital-Acquired Condition Reduction Program). We recognize that under our current timely claims filing policy, hospitals have up to 1 year from the date of discharge to submit a claim to us. However, in using claims data to calculate quality measure results for the CJR model, we will create claims data extracts approximately 90 days after the last discharge date in the applicable performance period. For example, for model year one of the CJR model, the last discharge date in the performance period for the THA/TKA Complications measure (NQF #1550) is March 31, 2016, so we would create the data extract on or around June 30, 2016 and use that data to calculate the measure result for the April 1, 2013 to March 31, 2016 performance period. Participant hospitals are already familiar with this 90-day claims ''run-out'' period, which we apply when creating data extracts for all of our claims-based outcome measures used in the HIQR, HVBP, HRRP Programs, and the Hospital-Acquired Condition Reduction Program (for example, see 77 FR 53399 through 53401 as this policy is applied for HRRP and 78 FR 50725 through 50727 as this policy is applied in the Hospital-Acquired Condition Reduction Program).

*Comment:* A commenter requested clarification regarding the 1-year difference in performance periods for FY 2016's HIQR Program and the proposed performance periods for the CJR model (80 FR 41290, Table 17). The clarification request was specific to the THA/TKA Complications measure (NQF #1550) where they indicated that the FY 2016 HIQR Program THA/TKA Complications measure (NQF #1550) is April 2012 through March 2015 and for the CJR model THA/TKA Complications measure (NQF #1550) performance period is April 2013 through March 2016.

*Response:* Table 17 of the proposed rule (80 FR 41290), had set forth the performance periods for each of the proposed quality measures for the 5 performance years of the CJR model. As we state in section III.D.5. of this final rule, we are finalizing Table 32 with respect to the THA/TKA Complications

measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166) with the performance periods as previously set forth, but we are not finalizing the THA/TKA Readmissions measure (NQF #1550). In addition, we want to provide further clarification on the CJR model performance periods for the THA/TKA Complications measure (NQF #1550) as compared to the performance periods that will be used in the HIQR Program. As we stated in the proposed rule (80 FR 41290), the performance periods are intended to align with the public reporting timeline for this measure in the HIQR Program. For example, for the first performance year of the CJR model, the performance period of the THA/TKA Complications measure (NQF #1550) is April 1, 2013 through March 31, 2016. When we are calculating reconciliation payment determinations for model year one (that is, CY 2016) during the spring of 2017, we will be using quality measure data that are the most currently available, which will be from the April 1, 2013 through March 31, 2016 performance period for the THA/TKA Complications measure (NQF #1550). The HIQR Program will be using data from the same period to prepare for public reporting on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) in July 2017. When information on each participant hospital's performance in the CJR model will be publicly reported on *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*) in July 2017, the performance period for the THA/TKA Complications measure (NQF #1550) will align with the performance period used for the same measure in the HIQR Program. We believe that aligning the performance periods for the THA/TKA Complications measure (NQF #1550) in this manner will reduce the potential for confusion among users of the Hospital Compare Web site (*http://www.hospitalcompare.hhs.gov/*) and also ensure that the CJR model uses the most currently available measure results for calculating participant hospital reconciliation payment determinations. The CJR model will not use measure results data from the HIQR Program's July 2016 public reporting, which will be April 1, 2012 through March 31, 2015 for the THA/TKA Complications measure (NQF #1550), for the reasons previously described.

*Comment:* A commenter urged CMS to rapidly disclose hospitals' results on the THA/TKA PRO–PM to the public.

*Response:* We will not publicly report the voluntary patient-reported outcomes and limited risk variable data during or after this model. We note that the data will be used to complete measure development of the THA/TKA patient reported performance based outcome measure. We intend to acknowledge those hospitals that are voluntarily submitting PRO and limited risk variable data via an icon or symbol by the hospital's name on the *Hospital Compare* Web site. If we consider adopting such a measure for the CJR model, we would do so through rulemaking.

*Final Decision:* After consideration of the public comments we received, we are finalizing our proposals to publicly report quality measure results each year on the *Hospital Compare* Web site (*http://www.hospitalcompare.hhs.gov/*), including acknowledgment of hospitals that voluntarily submit data for the functional status measure with an icon on the *Hospital Compare* Web site. We are finalizing the public reporting of measure results each year for the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0166). Measure results for the THA/TKA Readmissions measure (NQF #1551) will not be publicly reported each year since we are not finalizing this measure. We have also provided further clarification as to the sharing of quality measure results with participant hospitals, the use of confidential reports that participant hospitals will receive, and the opportunity they will have to review and submit correction requests for their measure result calculations prior to public reporting on *Hospital Compare* Web site.

TABLE 32—SUMMARY OF FINALIZED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE CJR MODEL

| Measure title | CJR Model year | | | | |
|---|---|---|---|---|---|
| | 1st | 2nd | 3rd | 4th | 5th |
| THA/TKA Complications* | April 1, 2013–March 31, 2016. | April 1, 2014–March 31, 2017. | April 1, 2015–March 31, 2018. | April 1, 2016–March 31, 2019. | April 1, 2017–March 31, 2020. |
| HCAHPS** | July 1, 2015–June 30, 2016. | July 1, 2016–June 30, 2017. | July 1, 2017–June 30, 2018. | July 1, 2018–June 30, 2019. | July 1, 2019–June 30, 2020. |

*Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

**Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166).

This final policy is set forth at § 510.400.

*E. Data Sharing*

1. Overview

In section III.E. of the proposed rule, we proposed to provide data to the hospital participants of the CJR model. We have experience with a range of efforts designed to improve care coordination for Medicare beneficiaries, including the Medicare Shared Savings Program (Shared Savings Program), Pioneer ACO Model, and BPCI, all of which make certain data available to participants. In section III.C.2. of the proposed rule, we proposed a model to financially incentivize hospitals, through retrospective bundled payments, to engage in care redesign efforts to improve quality of care and reduce spending for the aggregate Part A and B FFS spending for beneficiaries included in the model during the inpatient hospitalization and 90 days post-discharge. Given this, we expressed our belief that it is necessary to provide historical and ongoing claims data representing care furnished during episodes of care for LEJRs to hospitals so that they can, among other things, adequately structure their care pathways, coordinate care for beneficiaries, and estimate acute inpatient and PAC spending within LEJR episodes.

As noted previously, this would not be the first instance in which we have provided claims data to entities participating in a CMS model or program. For example, participants in Shared Savings Program initially receive aggregate information on their historical financial performance as well as quarterly data throughout their tenure in the program. In addition, Shared Savings Program ACOs receive certain beneficiary-identifiable claims information in accordance with our regulations. (For more information, see

the November 2, 2011 final rule titled ''Medicare Program; Medicare Shared Savings Program: ACOs'' (76 FR 67844 through 67849)). The Shared Savings Program final rule noted that while an ACO may have complete information for the services it provides or coordinates on behalf of its FFS beneficiary population, it may not have access to complete information on a FFS beneficiary who chose to receive services, medications or supplies from non-ACO providers and suppliers. Thus, we decided to provide ACOs participating in the Shared Savings Program with an opportunity to request CMS claims data on the premise that more complete beneficiary-identifiable information would enable practitioners in an ACO to better coordinate and target care strategies. Recently, we noted that the ACOs participating in the Shared Savings Program have reported that the beneficiary identifiable claims data that they receive from us are being used effectively to better understand the FFS beneficiaries that are receiving services from their providers. These data give ACOs valuable insight in to patterns of care for their beneficiary population; enable them to improve care coordination among and across providers and suppliers and sites of care, including providers and suppliers and sites of care not affiliated with the ACO; and allow them to identify and address gaps in patient care. (For more information, see the Medicare Shared Savings Program final rule (80 FR 32733 through 32734.)

Similarly, participants in the Pioneer ACO model can request historical claims data of beneficiaries aligned with the particular Pioneer ACO entity, and the entities continue to receive certain ongoing data regarding the services furnished to those beneficiaries. (For more information, see the CMS Web site *http://innovation.cms.gov/Files/fact-sheet/Pioneer-ACO-Model-Beneficiaries-Rights-Fact-Sheet.pdf*). In addition, we provide BPCI participants with the opportunity to request beneficiary-level claims data regarding their own patients, both for the historical period of 2009 to 2012 that was used to set baseline prices for entities participating in BPCI, as well as ongoing monthly claims feeds containing Medicare FFS claims for beneficiaries that could have initiated an episode of care for that particular BPCI participant. These monthly claims feeds provide BPCI participants with data for both acute and PAC spending for beneficiaries that could have initiated an episode of care at that BPCI participant.

As noted in the proposed rule, based on our experience with these efforts, we believe that providing a similar opportunity for hospitals participating in the CJR model to request data is necessary for participant hospitals to have the relevant information to allow for practice changes supported by CJR and to identify services furnished to beneficiaries receiving LEJRs under the model. Specifically, providing participant hospitals with certain claims and summary information on beneficiaries in accordance with established privacy and security protections would improve their understanding of the totality of care provided during an episode of care. With this greater understanding, we anticipate that hospitals would be better equipped to evaluate their practice patterns and actively manage care delivery so that care for beneficiaries is better coordinated, quality and efficiency are improved, and payments aligned more appropriately to the medically necessary services beneficiaries have a right to receive. We also expect that providing this data to CJR participants will benefit beneficiaries by allowing providers to use the data to improve care coordination activities in areas that may be currently lacking. However, we also noted our expectation that CJR hospitals are able to, or will work toward, independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services.

Accordingly, we believe that making certain data available to CJR hospitals, as we do with ACOs participating in the Shared Saving Program and Pioneer ACO Model, would help them to monitor trends and make needed adjustments in their practice patterns. In order for CJR participants to understand and track their care patterns, we proposed to provide the participants with beneficiary-level claims data for the historical period used to calculate a CJR hospital's target price as well as ongoing quarterly beneficiary-identifiable claims data in response to their request for such data in accordance with our regulations. Given that the CJR model also proposes to incorporate regional pricing in the calculation of target prices, we also proposed to provide participants with aggregate regional data.

*Comment:* Some commenters noted that CMS expects that hospitals are able to, or will work toward, independently identifying and producing their own data. These commenters concurred that hospitals were making these efforts, but noted that there were challenges in doing so.

*Response:* We appreciate hospitals' efforts to independently identify and produce performance data, and believe that our proposal, which makes certain financial performance data available, will be supportive of these efforts.

2. Beneficiary Claims Data

In the proposed rule we noted that, based on our experience with BPCI participants, we recognize that hospitals vary with respect to the kinds of beneficiary claims information that would be most helpful. While many hospitals located in MSAs that are selected for participation in CJR model may have the ability to analyze raw claims data, other hospitals may find it more useful to have a summary of these data. Given this, we proposed to make beneficiary claims information available through two formats.

First, for participant hospitals that lack the capacity to analyze raw claims data, we proposed to provide summary beneficiary claims data reports on beneficiaries' use of health care services during the baseline and performance periods. These reports would allow participant hospitals to assess summary data on their relevant beneficiary population without requiring sophisticated analysis of raw claims data. Such summary reports will provide tools to monitor, understand, and manage utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if the data provided by CMS to a particular hospital participant reflects that a certain PAC provider admits beneficiaries who then have significantly higher rates of inpatient readmissions than the rates experienced by other beneficiaries with similar care needs at similarly situated PAC providers, that may be evidence that the hospital could consider, among other things, the appropriateness of discharges to that provider, whether other alternatives might be more appropriate, and whether there exist certain care interventions that could be incorporated post-discharge to lower readmission rates.

Therefore, for both the baseline period and on a quarterly basis during a participant hospital's performance period, we proposed to provide participant hospitals with an opportunity to request summary claims data that would encompass the total expenditures and claims for an LEJR episode, including the procedure,

inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, PAC, and physician services for the hospital's beneficiaries whose anchor diagnosis at discharge was either MS DRG 469 or 470. We proposed that these summary claims aggregate data reports would also contain payment information, utilizing the categories listed for each episode triggered by a beneficiary as follows:

- Inpatient hospital.
- Outpatient hospital.
- Physician.
- Long-term care hospital (LTCH).
- IRF.
- SNF.
- HHA.
- Hospice.
- ASC.
- Part–B drug.
- Durable medical equipment (DME).
- Clinical laboratory.
- Ambulance.

These reports would likely include the following:

- Information such as admission and discharge date from the anchor hospitalization.
- The physician for the primary procedure, Medicare payments during the anchor hospitalization.
- Medicare payments during the PAC phase.
- Medicare payments for physician services would likely be included in these reports.

These summary claims data would reflect all Medicare Part A and Part B expenditures during the 90-day episodes, except for those claim types noted later in this section, as well as excluding expenditures related to those MS–DRGs that we proposed to be specifically excluded from the episode of care, as set forth in section III.B.2. of the proposed rule.

Alternatively, for hospitals with a capacity to analyze raw claims data, we would make more detailed beneficiary-level information available in accordance with established privacy and security protections. These data would enable hospitals to better coordinate and target care strategies for beneficiaries included in CJR episodes. For example, in the BPCI initiative, we provide participants with beneficiary-level claims data for all Part A and Part B services furnished to a beneficiary treated by that BPCI participant for all MS–DRGs included in an episode that the participant has selected for participation (See BPCI: Background on Model 2 for Prospective Participants, page 3 at *http://innovation.cms.gov/Files/x/BPCI_Model2Background.pdf.*)

These data include services furnished by the participant, as well as services furnished by other entities during the 30-, 60- or 90-day episode. For example, where the entity participating in BPCI is an acute care hospital, we provide beneficiary-level claims data for all Medicare Part A and B services and supplies furnished by the hospital during the inpatient admission, as well as all PAC services furnished to the beneficiary by the hospital or any other providers or suppliers.

The response from entities participating in BPCI has indicated that the availability of these data is necessary to monitor trends and pinpoint areas where care practice changes are appropriate, as well as assess the cost drivers during the acute and PAC periods of the episode. Thus, for the baseline period and on a quarterly basis during a hospital's performance period, we proposed to provide participant hospitals with an opportunity to request line-level claims data for each episode that is included in the relevant performance year, as described in section III.C. of the proposed rule.

For both the proposed summary claims data and the more detailed claims data formats, we proposed that the sets of these files would be packaged and sent to a portal in a ''flat'' or binary format for the individual participant hospitals to retrieve. Furthermore, the files would contain information on all claims triggered by a beneficiary in a participating CJR hospital.

Finally, we note that beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) would not be included in any beneficiary identifiable claims data shared with a hospital under our proposal.

We requested comments on these proposals as well as the kinds of data and frequency of reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

The following is a summary of the comments received and our responses.

*Comment:* Commenters supported CMS's proposal to make both historical baseline and updated beneficiary claims information available to hospitals participating in CJR both on a detailed line level and a summary basis. Commenters noted the importance of these data for such purposes as formulating processes and protocols to redesign care, developing networks with physicians, physician groups and PAC providers, establishing necessary clinical and administrative infrastructure during the pre-implementation period, and estimating potential savings associated with better care delivery.

*Response:* We appreciate and concur with these comments that support our proposal.

*Comment:* A commenter stated that participants should be provided both line-level and summary beneficiary claims information rather than just one data type or the other.

*Response:* We appreciate this suggestion and wish to clarify that we will make both line-level and summary beneficiary claims data available to participating hospitals upon request in accordance with established privacy and security protections.

*Comment:* Commenters opposed the proposal to exclude beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) from any beneficiary identifiable claims data shared with a hospital. Commenters noted that this information was vital for hospitals to understand the full risk associated with beneficiaries and was needed to identify appropriate care management methods. Some commenters expressed the view that hospitals should not be required to assume risk for beneficiaries where these data are not made available. Other commenters requested that CMS make available de-identified cost and claims data or aggregate payment data for these services. Moreover, some commenters recommended that CMS apply its waiver authority to make beneficiary-specific claims level substance abuse data available to hospitals or work with the Congress to create an exception to 42 CFR part 2 to provide claims level, identifiable data.

*Response:* Section 1115A of the Act does not authorize the waiver of the requirements under 42 CFR part 2. Moreover, our proposal to exclude this information is consistent with our usual treatment of these data with other similar CMS programs and models where providers must take on risk in managing the care of their beneficiaries, such as the Shared Savings Program and BPCI model. We would note that, based on our experience to date, we are unaware of this policy being a significant impediment to the operations of these efforts. We also appreciate the suggestions to make these data available in a de-identified manner. We have considered this option and are not currently aware of a means to make de-identified beneficiary-specific data available in a way that would provide useful information to participating hospitals without potentially making it

possible to identify beneficiaries. Similarly, we have also not identified a way in which to make meaningful aggregate data available on a limited basis without potentially compromising beneficiary confidentiality. However, we will continue to consider these comments and the feasibility of making such data available in a way that is both meaningful to participating hospitals and in compliance with 42 CFR part 2.

*Comment:* Commenters questioned the frequency, mechanisms, and content of the information we propose to make available to participant hospitals.

*Response:* These comments and our responses will be discussed in their respective sections, which follow.

*Final Decision:* After considering the public comments we received, we are finalizing the proposal at § 510.300(d) to make available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals. We are also finalizing our proposal to exclude information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) from any beneficiary identifiable claims data shared with a hospital at this time.

3. Aggregate Regional Data

Because we proposed to incorporate regional pricing data in the creation of prices for CJR, as set forth in section III.C.4. of the proposed rule, we noted our belief that it will also be necessary to provide comparable aggregate expenditure data available for all claims associated with MS–DRGs 469 and 470 for the census region in which the participant hospital is located. As noted in section III.C.4.b.(5) of the proposed rule, we proposed that a hospital's target price will be determined based on a blend of its own historical expenditures as well as regional pricing data of all other hospitals in its region. Thus, we also proposed to provide CJR hospitals with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries whose anchor diagnosis at discharge was either MS–DRG 469 or 470 (and would have initiated a CJR episode if discharged from a CJR hospital) in their census region. These data would not include beneficiary-identifiable claims data, but would provide high-level information on the average episode spending for MS–DRGs 469 and 470 in the region in which the participant hospital is located. We requested comments on these proposals as well as the kinds of aggregate data and frequency of data reports that would be most helpful to the hospitals' efforts in coordinating care, improving health, and producing efficiencies.

The following is a summary of the comments received and our responses.

*Comment:* Commenters supported the proposal to make expenditure data available for claims associated with MS–DRGs 469 and 470 for the census region in which the participant hospital is located, for example, that these data would be critical to hospitals in tracking their performance relative to benchmarks over time or would allow them to anticipate future changes in target pricing. A commenter noted that the proposal to provide 3 years of historical claim-level data is sufficient for purposes of this program and expressed support for CMS' proposal to include both Part A and Part B spending data. However, another commenter expressed reservations about the usefulness of high-level aggregate spending data by spending census region.

*Response:* We concur with the comments supporting our proposal to make aggregate regional data available to hospitals. We recognize that some hospitals might prefer to have more detailed data rather than aggregated data. However, we believe the data we will be making available should be helpful both as a performance benchmark for participating hospitals relative to their peers as well as to better understand their financial performance expectations, particularly given that regional pricing data will be incorporated for purposes of determining their target prices.

*Comment:* The comments we received on the frequency with which aggregate regional data would be made available to hospitals were often requests for us to make these data available more frequently, such as on a monthly basis.

*Response:* Our response to these comments is discussed later in section III.E.5. of this final rule.

*Comment:* With respect to data content, we received a suggestion that these data contain enough detail to identify potential opportunities for improvement. A commenter suggested that CMS use the BPCI data extracts as a starting point for CJR, since they were satisfactory to BPCI participants. Specific requests included proposals that the data reflect a rolling 18-month period, include separate subsets for outpatient physical and occupational therapy and for comprehensive outpatient rehabilitation facility (CORF) services, and that CMS provide a detailed description of the calculations needed to derive the regional target prices. Several comments requested that the data be broken down by MS–DRG as follows:

- Total normalized episode expenditures.
- Normalized episode expenditures within cost categories (anchor inpatient, SNF, HHA, IRF, LTCH readmissions, professional services, other).
- Variability metrics related to the total normalized episode expenditures (standard deviation, 95th percentile, 99th percentile, etc.).
- Episode counts.
- Variability metrics surrounding episode counts (what is the mean number of episodes at a hospital in the region, the standard deviation, the 95th or 99th percentile, etc.).
- Utilization percentages for key services (what percentage of episodes had SNF utilization, IRF, LTCH, HHA, readmissions).
- Percentage of episodes that were non-elective (for example, using the quality metric specification exclusions methodology).

*Response:* We appreciate the comments we received on the kinds of data that might be helpful to participating hospitals, and agree with the comment that the regional data we provide should contain enough detail to identify potential opportunities for improvement.

*Final Decision:* We are finalizing our proposal to provide CJR hospitals with aggregate data on the total expenditures during an acute inpatient stay and 90-day post-discharge period for all Medicare FFS beneficiaries whose anchor diagnosis at discharge was either MS–DRG 469 or 470 (and would have initiated a CJR episode if discharged from a CJR hospital) in their census region. We will also consider the range of comments we received on the additional kinds of data elements and formats that would be most useful to participating hospitals. In the event we consider adopting additional elements or formats for these data, we will provide further guidance, potentially through rulemaking if warranted.

4. Timing and Period of Baseline Data

As stated in the proposed rule, we considered various options for the timing of providing baseline data to CJR participant hospitals. We considered provision of data prior to the proposed start date of the model as well as providing data to participants at the point of the first payment reconciliation (described in section III.C.6. of the proposed rule). We proposed to make baseline data available to hospitals participating in CJR no sooner than 60 days after the proposed start date of the model. We noted our recognition that

these data are important to the abilities of CJR participant hospitals to estimate costs, coordinate care, and identify areas for practice transformation, and that early release of this data can facilitate their efforts to do so. We also noted our view that hospitals will view the CJR effort as one involving continuous improvement. As a result, changes initially contemplated by a hospital could be subsequently revised based on updated information and experiences. We also indicated that while we would like to be able to make data available as soon as possible once the model had begun, we did not believe that these baseline data must be immediately available upon the start date of the model as hospitals can begin considering improvements that would enhance their ability to better coordinate care and increase efficiencies in the absence of these data. Therefore, we proposed to begin making baseline data available to CJR hospitals within 60 days of CMS' receipt of the request by the participant hospital for such data, in a form, time, and manner of such requests to be determined by CMS and announced at a later date. Further requests would not be accepted until the model had begun. We sought comments on this proposal.

In the proposed rule, we also discussed which period of baseline data should be shared with hospitals, for example, whether the data should represent a single year, or some longer period such as a 3-year period or more. We expressed our belief that to be most useful, the baseline information should be recent enough to reflect current practices yet of a sufficient duration to reflect trends in those recent practices. For example, 1 year of data would likely reflect a hospital's most current practices, but would not be helpful for purposes of identifying trends. In contrast, 3 years of data could both reflect a hospital's most recent performance and recent performance trends. Moreover, we noted that making data available for a 3-year period aligned with our proposal to set a target price based on a 3-year period of baseline data, which is a factor in assessing CJR hospitals' performance (see section III.C. of this final rule). That is, if a hospital has access to baseline data for the 3-year period used to set its target price, then it would be able to assess its practice patterns, identify cost drivers, and ultimately redesign its care practices to improve efficiency and quality.

We alternatively considered making data available for an even longer historical period—for example, 4 or 5 years. However, we questioned the usefulness of information that is older than 3 years for purposes of changes contemplated for current operations. Accordingly, in our proposed rule, we proposed to make available baseline data for up to a 3-year period. We indicated that we would limit the content of this data set to the minimum data necessary for the participant hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. This period would encompass up to the 3 most recent years for which claims data are available for the hospital and would align with the baseline period we proposed to utilize to establish target prices, as noted previously. We sought comments on our proposal and invited comments on alternative time periods that could better help hospitals evaluate their practice patterns and actively manage care delivery so that care is better coordinated, quality and efficiency are improved, and costs are better controlled.

The following is a summary of the comments received and our responses.

*Comment:* The comments we received supported our proposal to make 3 years of baseline data available to participating hospitals.

*Response:* We appreciate and concur with those comments.

*Comment:* Many commenters opposed the proposal to make baseline data available to hospitals participating in CJR no sooner than 60 days after the proposed start date of the model. Commenters expressed concern that this proposal would allow insufficient time to prepare and that hospitals should be provided with historical claims data in advance of the start data; typically, 3 to 6 months prior to implementation with some commenters recommending up to 1 year prior to implementation.

Commenters indicated that data would be needed sooner than was proposed for reasons such as participating hospitals would need the data and time to analyze claims for purposes of identifying opportunities for care redesign, formulate processes and protocols to redesign care, assess the performance of potential partners, develop networks with physicians and PAC providers, and establish necessary clinical and administrative infrastructure. Further, hospitals might not have the in-house resources to analyze the data and thus need to use consulting resources for these purposes. Commenters noted that activities such as these could take several months to complete once the data were made available.

Some commenters also noted that the absence of downside risk does not diminish the need for access to data in advance of the CJR performance period. Moreover, commenters pointed to other CMS/CMMI efforts where data were made available prior to implementation. For example, under the BPCI model, participants received historical claims data feeds prior to the start of the program, and had approximately 12 months from receiving the data prior to enrollment in the program.

Commenters expressed concerns that insufficient time for preparation and lack of data for preparatory analysis, prior to start, could hinder a hospital's ability to effectively coordinate and ensure smooth transitions across the continuum of care for beneficiaries undergoing LEJR procedures. As discussed elsewhere in this final rule, several commenters recommended that the program be delayed so that data could be made available in advance of implementation.

*Response:* We appreciate the concerns and reasons expressed by commenters for opposing our proposal to make baseline data available to hospitals participating in CJR no sooner than 60 days after the initially proposed start date of the model, as well as suggestions for when these data should be made available. We have carefully considered the timeframes for making these data available, and have made other modifications to our proposed rule that should assist in mitigating the concerns commenters have raised on this issue. First, as discussed in section III.C.2.a. of this final rule, we are delaying the start date of the model to April 1, 2016, which is, in part, in response to when data could be made available. Second, as discussed in III.C.8. of this final rule, we are also reducing the potential risk to participating hospitals by lowering the stop-loss limit from 10 percent to 5 percent.

*Final Decision:* After considering the public comments we received, we are finalizing our proposal to make 3 years of baseline data available to hospitals and intend to make these data available, upon request, before the April 1, 2016 start date.

5. Frequency and Period of Claims Data Updates for Sharing Beneficiary-Identifiable Claims Data During the Performance Period

As indicated in our proposed rule, we believe that the availability of periodically updated beneficiary-identifiable claims data will assist hospitals participating in CJR to identify areas where they might wish to change their care practice patterns, as well as

monitor the effects of any such changes. With respect to these purposes, we have considered what would be the most appropriate period for making updated claims information available to hospitals, while complying with the HIPAA Privacy Rule's ''minimum necessary'' provisions standard. We stated our belief that quarterly claims data updates align with a 90-day episode window. Moreover, as a larger episode window would be included, the claims data would be more representative of total costs and hence more useful to hospitals as they consider long-term practice changes. Accordingly, in our proposed rule, we proposed to make updated claims data available to hospitals upon receipt of a request for such information that meets CMS's requirements to ensure the applicable HIPAA conditions for disclosure have been met, as frequently as on a quarterly basis. We sought comments on this proposal.

Related to this is the period of claims that would be represented in each update. For example, as stated in our proposed rule, we considered limiting this period to 3 months of data, which aligns with the frequency with which we would make updated claims data available. However, other than this alignment, we did not see additional reasons for artificially limiting the period to this extent. Alternatively, we considered providing an updated dataset as frequently as each quarter that would include data from up to the previous 6 quarters. We noted our belief that this level of cumulative data would offer more complete information and allow better trend comparisons.

Accordingly, we proposed to make beneficiary-identifiable and aggregate claims data available that would represent up to 6 quarters of information upon receipt of a request for such information that meets the requirements of the HIPAA Privacy Rule. We noted that we intended for the data for this model to be consistent with our proposed performance year of (January 1 through December 31). To accomplish this for the first year of CJR (2016), we proposed to provide, upon request and in accordance with the HIPAA Privacy Rule, claims data from January 1, 2016 to June 30, 2017 on as frequently as a running quarterly basis, as claims were available. For each quarter and extending through June 30, 2017, we proposed that participants during that first year would receive data for up to the current quarter and all of the previous quarters going back to January 1, 2016. These datasets would contain all claims for all potential episodes that were initiated in 2016 and capture a sufficient amount of time for relevant claims to have been processed. We noted in our proposed rule that we would limit the content of this data set to the minimum data necessary for the participating hospital to conduct quality assessment and improvement activities and effectively coordinate care of its patient population. We sought comment on our proposal.

The following is a summary of the comments received and our responses.

*Comment:* Commenters noted the importance of hospitals being provided timely data. Some commenters requested real time data to enable hospitals to quickly identify and appropriately intervene to manage cost and quality or to achieve the goals of the program. Another commenter noted that having data from the most recent quarters would enable them to understand their current performance.

While some commenters supported the proposal to make data available on a quarterly basis, most of the comments we received on this topic indicated that data would be needed on a more frequent basis—specifically, on a monthly basis. Commenters suggested that monthly data would be needed for hospitals to react more quickly and to make course changes in response to changes in cost, quality, and utilization. A commenter noted that monthly updates would be needed for tracking patients whose highest utilization is in the first 30 days after their surgery. Another commenter suggested that in addition to facilitating hospitals' ability to implement the model, having more frequent data updates would encourage provider engagement in the program. Several comments also noted and requested that we make data available on a monthly basis as is done with the BPCI model.

*Response:* We appreciate and concur with comments on the importance of being provided timely data, such as claims data during the most recent quarters, and the usefulness of these data to hospitals' ability to understand, monitor, and adjust their performance. We also appreciate commenter's requests for more frequent data updates, but are not persuaded that access to real-time data is needed for hospitals to monitor and understand trends in their practice patterns. We would also note that making these data available on a real-time basis would not be feasible for CMS. Accordingly, we are modifying our proposal from making these data available on a quarterly basis to making these data available ''no less frequently'' than on a quarterly basis with the goal of making these data available on as frequently as a monthly basis if practicable. Thus, we are revising § 510.300 (d) to state ''The minimum data necessary to achieve the goals of the CJR model, as determined by CMS, may be provided under this section for a participant hospital's baseline period and no less frequently than on a quarterly basis throughout the hospital's participation in the CJR model.'' We would note that this modification would apply to both beneficiary-identifiable claims data (line- and summary-level) and aggregate regional data that was discussed earlier in section III.C.4. of this final rule. We would also note that, because we are delaying our start date from January 1 to April 1, 2016, we will be providing upon request and in accordance with the HIPAA Privacy Rule, claims data for episodes that began on or after April 1, 2016 (rather than January 1, 2016) and ended on or before December 31. In subsequent years, data for each performance year would reflect episodes that began on or after January 1 of that year and ended on or before December 31 of that year. Further, in our proposed rule, we had proposed to make up to six quarters of data available to participating hospital. We wish to clarify that, in order to make these data most meaningful to participating hospitals, we plan to synchronize the availability of these data with the annual payment reconciliation process, which will occur in the second quarter of the year following the performance year. For example, these data could then represent four quarters for the first year and five quarters thereafter.

*Comment:* Commenters requested that data be made available automatically without a specific request for the data. These commenters typically pointed to the potential for additional administrative burden associated with requesting the data. As an alternative, commenters suggested that hospitals receive data upon acceptance or subscribe to receive data for the duration of the model. A commenter suggested that CMS establish a data delivery sign-up process under which hospitals can elect to receive beneficiary claims data only, summary data only, or both beneficiary claims and summary data on an ongoing basis. Under this system, hospitals could change their election at any point during the model as they develop data handling and analytical capability. Another commenter suggested that CMS make data available through secure portals for providers (or their designees) to access.

*Response:* We wish to limit administrative burden for hospitals participating in the model and wish to clarify that while we will make data

available to hospitals only upon request, hospitals would be able to make a single request for these data at the start of the model that would make data available to them for the duration of their participation or until they notify CMS that they no longer wish to receive these data. To be consistent with the HIPAA Privacy Rule's ''minimum necessary'' standard, we will continue to make data available only in response to a request.

*Final Decision:* After consideration of the public comments we received, we are modifying our proposal at § 510.300 (d) to no longer limit the availability of updated data to a frequency ''no more often than once a quarter'' to instead ''no less frequently than on a quarterly basis'' with the goal of making these data available as frequently as on a monthly basis if practicable. We also clarify that in order to receive data during their participation in the model, a hospital need only make a single initial request rather than multiple periodic requests.

6. Legal Permission To Share Beneficiary-Identifiable Data

As stated in our proposed rule, we recognize that there are a number of issues and sensitivities surrounding the disclosure of beneficiary-identifiable health information, and note that a number of laws place constraints on sharing individually identifiable health information. For example, section 1106 of the Act bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the HIPAA Privacy Rule permits this proposed disclosure of individually identifiable health information by us.

We proposed to make participant hospitals financially responsible for services that may have occurred outside of the hospital during the 90-day post-discharge period. Although we expect hospitals to be actively engaged in post-discharge planning and other care during the 90-day post-discharge period for beneficiaries receiving LEJRs, as discussed in section III.A. of the proposed rule, we stated our belief that it was necessary for the purposes of the CJR model to provide participant hospitals with beneficiary-level claims data, either in summary or line-level claim formats for a 3-year historical period as well as on a quarterly basis during the performance period. We believe that these data constitute the minimum information necessary to enable the participant hospital to understand spending patterns during the episode, appropriately coordinate care, and target care strategies toward individual beneficiaries furnished care by the participant hospital and other providers and suppliers.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, including hospitals, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called ''protected health information'' or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule. The Medicare FFS program, a ''health plan'' function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. The hospitals and other Medicare providers and suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they conduct (or someone on their behalf conducts) one or more HIPAA standard transactions electronically, such as for claims transactions. In light of these relationships, we believe that the proposed disclosure of the beneficiary claims data for an acute inpatient stay plus 90-day post-discharge episode where the anchor diagnosis at discharge was MS–DRG 469 or 470 would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for ''health care operations'' purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed, the PHI pertains to that relationship, and the recipient will use the PHI for a ''health care operations'' function that falls within the first two paragraphs of the definition of ''health care operations'' in the HIPAA Privacy Rule (45 CFR 164.506(c)(4)).

The first paragraph of the definition of health care operations includes ''conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines,'' and ''population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination'' (45 CFR 164.501).

Under our proposal, hospitals would be using the data on their patients to evaluate the performance of the hospital and other providers and suppliers that furnished services to the patient, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their patients. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as ''health care operations'' under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. Hence, as previously discussed, we believe that this provision is extensive enough to cover the uses we would expect a participant hospital to make of the beneficiary-identifiable data and would be permissible under the HIPAA Privacy Rule. Moreover, our proposed disclosures would be made only to HIPAA covered entities that have (or had) a relationship with the subject of the information, the information we would disclose would pertain to such relationship, and those disclosures would be for purposes listed in the first two paragraphs of the definition of ''health care operations.''

When using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make ''reasonable efforts to limit'' the information that is used, disclosed or requested the ''minimum necessary'' to accomplish the intended purpose of the use, disclosure or request (45 CFR 164.502(b)). We believe that the provision of the proposed data elements listed previously would constitute the minimum data necessary to accomplish the CJR model goals of the participant hospital.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act applies when the federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply (5 U.S.C. 552a(b)).

''Routine uses'' are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in the proposed rule was collected and may be disclosed in accordance with the routine uses applicable to those records.

Notwithstanding these exceptions, in the proposed rule, we stated our belief

that it would be appropriate to provide some form of notice to Medicare beneficiaries about sharing these data. Based on our experiences with data sharing in other CMS programs and models, we proposed a strategy for notifying beneficiaries of claims data sharing in the proposed rule, and in order to provide meaningful beneficiary choice over claims data sharing with the participant hospitals in CJR. We considered both ''opt-in'' and ''opt-out'' options for beneficiaries with respect to data sharing in CJR. In our proposed rule, we noted that an advantage of an opt-in method was that consumers have consistently expressed a desire that their consent should be sought before their health information may be shared (Schneider, S. et al. ''Consumer Engagement in Developing Electronic Health Information System.'' Prepared for: Agency for Healthcare Research and Quality, July 2009, at 16. Available at: *http://healthit.ahrq.gov/ahrq-funded-projects/consumer-engagement-developing-electronic-health-information-systems*).

In the proposed rule, we also noted that an opt-out method has been used successfully in most systems of electronic exchange of information because it is significantly less burdensome on patients and providers while still providing an opportunity for patients to exercise control over their data. Thus, in our proposed rule, we proposed to use an ''opt-out'' approach to provide beneficiaries with the opportunity to decline claims data sharing directly through 1–800-Medicare, rather than through the participant hospital. We also proposed to provide advance notification to all Medicare beneficiaries about the opportunity to decline claims data sharing with entities participating in CMS programs and models through CMS materials such as the Medicare & You Handbook. The Handbook would include information about the purpose of the model, describe the opportunity for participants to request beneficiary identifiable claims data for health care operations purposes, and provide instructions on how beneficiaries may decline claims data sharing by contacting CMS directly through 1–800–MEDICARE. The Handbook would also contain instructions on how a beneficiary may reverse his or her preference to decline claims data sharing by contacting 1–800–MEDICARE.

In the proposed rule, we noted one advantage of these strategies was that 1–800–MEDICARE is a communication method to which beneficiaries have familiarity and broad exposure. It also has the capability for beneficiaries to use accessible alternative or appropriate assistive technology, if needed. Also, while many procedures in MS–DRGs 469 and 470 are planned in advance, some are emergent or unplanned procedures. Thus, asking the participant hospital to provide advance notification to the beneficiary, prior to the provision of services, may be inappropriate or impossible in certain circumstances. We indicated that we would continue to maintain a list of beneficiaries who have declined data sharing and ensure that their claims information is not included in the claims files shared with participants. Further, hospitals with patient portals or Blue Button® may have capability to garner patient input prior to discharge through a hospital intervention specific to patient and caregiver education, while also aiding the hospital to meet reporting requirements for other CMS programs, such as Meaningful Use under the EHR Incentive Program for Medicare Hospitals.

Finally, we proposed that participant hospitals in CJR would only be allowed to request beneficiary-identifiable claims data for beneficiaries who: (1) Have been furnished a billable service by the participant hospital corresponding to the episode definitions for CJR; and (2) have not chosen to opt-out of claims data sharing. A beneficiary that chose to opt-out of claims data sharing would only be opting out of the data sharing portion of the model. The decision to opt-out would not otherwise limit CMS' use of the beneficiaries' data, whether the beneficiary can initiate an episode, inclusion in quality measures, or inclusion in reconciliation calculations. Where a beneficiary chose to opt-out of claims data sharing, our data contractor would maintain a list of all HICNs that choose to opt-out of data sharing. We would monitor whether participant hospitals continue to request data on beneficiaries who have opted out of having their data shared and do not intend to make such data available in response to CJR such a hospital's request.

We requested comments on our proposals related to the provision of both aggregate and beneficiary-identifiable data to participant hospitals in CJR. We indicated that we were particularly interested in comments on the kinds and frequency of data that would be useful to hospitals, potential privacy and security issues, the implications for sharing protected health information with hospitals, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of their information. We also requested comments on whether it would be helpful to provide any such system of notices, since Medicare claims information and other electronic information is already routinely shared for many other purposes among health care providers and insurers, and generally is subject to HIPAA protections. We also proposed where available, the exchange of CMS beneficiary data with the local electronic health information exchange, a system that allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically in order to facilitate the hospitals ability to share timely patient data supporting improved patient referral, access, and care coordination across varied service settings.

The following is a summary of the comments received and our responses.

*Comment:* Several commenters requested that the range of providers with whom CMS shares data be expanded beyond participating hospitals, for example, to all CJR collaborators including physicians and PAC providers. A commenter suggested that hospitals should receive data, even if they were not in a participating MSA, in order to begin making improvements. Another commenter requested that researchers, entrepreneurs and/or health care consumers be provided data or a subset of these data. A commenter requested that a state be provided with the data provided to participating hospitals. This commenter noted that making these data available would assist the state in determining how such a payment model would work under their state Model. This commenter noted that the data would facilitate data-driven conversations with stakeholders around the state and assist in determining opportunities for improvement in their health care environment.

Commenters expressed views that expanding the availability of data would enable collaborators to be in a better position to improve their performance and management of patient care as well as ensure that care decisions are driven by patient needs rather than the potential financial risk of the hospital.

*Response:* We understand commenters' desire for us to expand the scope of entities that would receive beneficiary-identifiable claims data. However, we believe it is neither appropriate nor do we have the authority to expand the availability of these data beyond what we proposed. As indicated earlier, there are significant sensitivities and constraints

on our ability to make beneficiary-identifiable data available. We proposed to make these data available to hospitals participating in the model in recognition of and in compliance with these sensitivities and constraints. For example, we proposed to make these data available to hospitals as ''covered entities'' that had a relationship with a beneficiary under the HIPAA Privacy Rule provision that permits the disclosure of this information for ''health care operations'' purposes. Accordingly, requests for data from entities that are not participating in the model would not meet the required standards to receive these data. Thus, we do not believe that we can make data available under the model to outside entities such as researchers or states that might wish access to these data.

In the case of providers and suppliers (for example, physicians, PAC providers, etc.) that are collaborators with hospitals participating in the model, those providers and suppliers might be eligible to receive data under HIPAA provided that they had a relationship with the beneficiary. However, we do not believe it is appropriate for CMS to provide collaborators these data because hospitals are the entities designated under the model to assume risk and responsibility for a beneficiary's episode of care under the model. Accordingly, as the responsible entity (and as a covered entity under HIPAA), we believe that hospitals should decide what data they need to manage care and care processes with their collaborators and what data they may or may not wish to make available to those collaborators provided they are in compliance with the HIPAA Privacy Rule.

*Comment:* Commenters opposed our proposal to allow beneficiaries to opt out of having their data shared. Commenters pointed to difficulty in effectively managing care and improving outcomes for these beneficiaries in the absence of data. A commenter noted that when a hospital's episode volume is small, the impact of a single episode can have more significant financial consequences. Further, they expressed the view that access to complete data is important during the reconciliation process in order to validate changes in savings and gainsharing payments. A commenter noted that while beneficiaries can decline to have their data shared under the Shared Savings Program, few have elected this option. (We would note that in our December 2014 proposed rule for the Shared Savings Program (79 FR 72788), we indicated that approximately two percent of beneficiaries had declined to have their data shared.) The commenter also expressed the view that CMS was under no legal obligation to offer a data sharing opt out to beneficiaries and that the conditions for receiving data and potential criminal penalties should suffice to discourage misuse of the data. Some commenters pointed to other CMS programs and models where beneficiaries cannot opt out of having their data shared, for example, BPCI and the Hospital Readmissions Reduction Program (HRRP).

Some commenters suggested that CMS exclude from the model those beneficiaries who elect not to have their data shared. Another commenter recommended that CMS monitor the frequency with which beneficiaries opt out of sharing data and, if it reaches a certain threshold for a CJR participant, exclude those beneficiaries from payment calculations. Further, they requested that CMS seek stakeholder input on how to prevent providers from being disadvantaged by lack of data as well as the appropriate thresholds for excluding beneficiaries when data opt out has reached a certain level.

*Response:* We appreciate the desire among hospitals and other providers to have complete information on their assigned beneficiaries included in the CJR model. While in our proposed rule (80 FR41198), we stated our belief that it would be appropriate to provide some form of notice to Medicare beneficiaries about sharing their data, we agree with comments noting that we are not required by law to offer beneficiaries the choice to opt out of having their personal information shared with hospitals participating in the CJR model. Rather, the HIPAA Privacy Rule provides beneficiaries a right to request restrictions on the use of their data, but a covered entity, which includes the Medicare FFS program or a hospital participating in the model, may or may not choose to grant the requested restriction. We also concur with the comment that CMS does not offer beneficiaries the choice to opt out of having their data shared under either BPCI (see *https://innovation.cms.gov/Files/x/BPCI_Model2Background.pdf*, or *https://innovation.cms.gov/Files/slides/BPCI-Overview2-4.pdf*) or HRRP (see § 412.154(f)).

In consideration of the comments we received and our experience with programs and models such as BPCI, we have decided to provide participating hospitals with as complete data on their beneficiaries as is possible under the law. We believe that making these data available will enhance hospitals' ability to identify existing care patterns that need to be changed or strengthened as well as the kinds of strategies needed to improve their care practices so that they can be most successful under the model. Thus, we have decided to not finalize our initial proposal to allow beneficiaries the choice to opt out of having their data shared at this time. We would note, however, that this does not preclude beneficiaries from exercising their right to request restrictions on the use of their data either with the participant hospital or with CMS, which administers the Medicare FFS program, by contacting 1–800–Medicare, through which they can speak with a customer service representative who can address their concern.

*Final Decision:* We are not finalizing our proposal permitting beneficiaries the choice to opt out of having their beneficiary-identifiable data shared. We will make these data available to participant hospitals, upon request and in accordance with the HIPAA Privacy Rule. We will not, however, be providing beneficiary-identifiable data under this model to collaborators within the model or entities that are not participating in the model.

*Comment:* Commenters encouraged CMS to ensure its contractors that are responsible for making data available to participants provide accurate and complete data within acceptable timeframes. A commenter suggested the creation of an ombudsman to serve as a conduit for complaints and determining whether a contractor should be subject to a penalty. Another commenter suggested that if data were not delivered to a participant within a given period (for example, 90 days after the end of a calendar quarter), then payments to the participant should be increased by some percentage (for example, 5 percent) during the following quarter. Similarly, we also received a number of comments related to data sharing but not with respect to the CJR model. For example, some commenters expressed concerns with the quality and challenges of using data provided under the BPCI model.

*Response:* We appreciate the need for accurate, complete, and timely data and will work with our contractors to ensure they are achieving these goals according to the terms of their contracts. Likewise, consistent with the terms of their contracts, we will take appropriate corrective actions with contractors where performance falls short of expectations. While the model has not yet been implemented, we have no reason to expect that contractor performance should fall short of expectations and thus do not anticipate a need for a special ombudsman to address data complaints and assess

penalties. Moreover, given that the model is intended to encourage and reward participants for improving the efficiency and quality of care provided to beneficiaries undergoing LEJR procedures, we do not believe that it would be appropriate to increase payments to participants in response to less than satisfactory performance by administrative contractors, should it occur. Comments on data sharing under BPCI or other models or programs are outside the scope of this rule and we will not be addressing them.

*Final Decision:* In summary, we are finalizing our proposal at § 510.300(d) to make available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals. We are finalizing our proposal to exclude information that is subject to the regulations governing the confidentiality of alcohol and drug abuse patient records (42 CFR part 2) from any beneficiary identifiable claims data shared with a hospital. We are finalizing our proposal to make 3 years of baseline data available to hospitals and note our intent to make these data available prior to the April 1, 2016 start date. We are modifying our proposal at § 510.300 (d) to no longer limit the availability of updated data to a frequency no more often than once a quarter to ''no less frequently than on a quarterly basis''. We also clarify that in order to receive data during their participation in the model, a hospital need only make a single rather than multiple periodic requests. We are not finalizing our proposal permitting beneficiaries the opportunity to decline having their beneficiary-identifiable data shared. We will make these data available to participant hospitals, upon request and in accordance with the HIPAA Privacy Rule. However, under the CJR model, we will not be providing these data to collaborators within the model or entities that are not participating in the model.

*F. Monitoring and Beneficiary Protection*

1. Introduction and Summary

We proposed the CJR model as we believe it is an opportunity to improve the quality of care and that the policies of the model support making care more easily accessible to consumers when and where they need it, increasing consumer engagement and thereby informing consumer choices. For example, under this model we proposed certain waivers that would offer participant hospitals or their collaborators additional flexibilities with respect to furnishing telehealth services, post-discharge home visits, and care in SNFs, as discussed in section III.C.11. of this final rule. We believe that this model will improve beneficiary access and outcomes. Conversely, we do note that these same opportunities could be used to try to steer beneficiaries into lower cost services without an appropriate emphasis on maintaining or increasing quality. We direct readers to sections III.C.5. and III.D. of this final rule for discussion of the methodology for incorporating quality into the payment structure and the measures utilized for this model.

We believe that existing Medicare provisions can be effective in protecting beneficiary freedom of choice and access to appropriate care under the CJR model. However, because the CJR model is designed to promote efficiencies in the delivery of all care associated with LEJR procedures, providers may seek greater control over the continuum of care and, in some cases, could attempt to direct beneficiaries into care pathways that save money at the expense of beneficiary choice or even beneficiary outcomes. As such, we acknowledge that some additional safeguards may be necessary under the CJR model as providers and suppliers are simultaneously seeking opportunities to decrease costs and utilization. We believe that it is important to consider any possibility of adverse consequences to patients and to ensure that sufficient controls are in place to protect Medicare beneficiaries receiving LEJR related services under the CJR model.

2. Beneficiary Choice and Beneficiary Notification

We have proposed that hospitals in selected geographic areas will be required to participate in the model, and that individual beneficiaries will not be able to opt out of the CJR model when they receive care from a participant hospital in the model. We stated our belief that it is not appropriate or consistent with other Medicare programs to allow patients to opt out of a payment system that is unique to a particular geographic area. For example, the state of Maryland has a unique payment system under Medicare, but that payment system does not create an alternative care delivery system, nor does it in any way impact beneficiary decisions. We also stated our belief that an inability to opt out of a payment system does not limit beneficiary choice as all covered Medicare services remain available under the model. We stated that we did not believe that an ability to opt out of the payment system was germane to beneficiary decisions because this model does not change beneficiary cost-sharing. We also stated our belief that full notification and disclosure of the payment model and its possible implications is critical for beneficiary understanding and protection, given that under all payment systems it is important to create safeguards for beneficiaries to ensure that care recommendations are based on clinical needs and not inappropriate cost savings. It is also important for beneficiaries to know that they can raise any concerns with their physicians, with 1–800–MEDICARE, or with their local QIOs.

This model does not limit the ability to choose among Medicare providers or the range of services available to the beneficiary. Beneficiaries may continue to choose any Medicare participating provider, or any physician or practitioner who has opted out of Medicare, with the same costs, copayments and responsibilities as they have with other Medicare services regardless of whether the provider or supplier is a participant hospital or has entered into a sharing arrangement with a participant hospital. Physicians and hospitals may identify and recommend ''preferred providers,'' a term used to include both providers and suppliers, which may include but are not limited to CJR collaborators with sharing arrangements with the participating hospital, as long as such recommendations do not result in violations of current laws or regulations. However, participant hospitals may not restrict beneficiaries to any such list of preferred or recommended providers/suppliers and must clearly advise beneficiaries that their choices are not constrained. Moreover, hospitals may not charge any CJR collaborator a fee to be included on any list of preferred providers or suppliers, nor may the hospital accept such payments, which would be considered to be outside the realm of risk-sharing agreements. Thus, this proposed payment model does not create any restriction of beneficiary freedom to choose providers and suppliers, including surgeons, hospitals, PAC or any other providers or suppliers.

As participant hospitals redesign care pathways, it may be difficult for providers and suppliers to sort individuals based on health care insurance and to treat them differently. We anticipate that care pathway redesign occurring in response to the model will increase coordination of care, improve the quality of care, and decrease cost for all patients, not just for Medicare beneficiaries. This anticipated

change in the delivery of care to all patients may further promote consistent treatment of all beneficiaries.

We stated our belief that beneficiary notification and engagement is essential because there will be a change in the way participating hospitals are paid. We stated our belief that appropriate beneficiary notification should explain the model, advise patients of both their clinical needs and their care delivery choices, and should clearly specify that any non-hospital provider or supplier holding a risk-sharing agreement with the hospital should be identified to the beneficiary as a ''financial partner of the hospital for the purposes of LEJR services.'' These policies seek to enhance beneficiaries' understanding of their care, improve their ability to share in the decision making, and ensure that they have the opportunity to consider competing benefits even as they are stated with cost-saving recommendations. We stated our belief that appropriate beneficiary notification should do all of the following:

- Explain the model and how it will or will not impact their care.
- Inform patients that they retain freedom of choice to choose providers and services.
- Explain how patients can access care records and claims data through an available patient portal and through sharing access to caregivers to their Blue Button® electronic health information.
- Advise patients that all standard Medicare beneficiary protections remain in place. These include the ability to report concerns of substandard care to QIOs and 1–800–MEDICARE.

After carefully considering the appropriate timing and circumstances for the necessary beneficiary notification, we proposed in the preamble that participating hospitals must require all providers and suppliers who execute a sharing arrangement with a participant hospital to share certain notification materials, to be developed or approved by CMS, that detail this proposed payment model before they order an admission for joint replacement for a Medicare FFS patient who would be included under the model. Participant hospitals must require this notification as a condition of any sharing arrangement. We also proposed in the preamble that where a participant hospital does not have sharing arrangements with providers or suppliers that furnish services to beneficiaries during a CJR episode of care, or where the admission for joint replacement for a Medicare FFS patient who would be included under the model was ordered by a physician who does not have a sharing arrangement, the beneficiary notification materials must be provided to the beneficiary by the participant hospital. However, we proposed text regulations that would require this notification by the hospital in all instances, a requirement we will keep in this final rule. The purpose of this proposed policy is to ensure that all beneficiaries that initiate a CJR episode receive the beneficiary notification materials, and that they receive such materials as early as possible. We stated our belief that this proposal targets beneficiaries for whom information is relevant, and increases the likelihood that patients will become engaged and seek to understand the model and its potential impact on their care.

We noted that beneficiaries are accustomed to receiving similar notices of rights and obligations from healthcare providers prior to the start of inpatient care. However, we also considered that this information might be best provided by hospitals at the point of admission for all beneficiaries, as hospitals provide other information concerning patient rights and responsibilities at that time. We invited comment on ways in which the timing and source of beneficiary notification could best serve the needs of beneficiaries without creating unnecessary administrative work for providers. We stated our belief that this notification is an important safeguard to help ensure that beneficiaries in the model receive all medically necessary services, but it is also an important clinical opportunity to better engage beneficiaries in defining their goals and preferences as they share in the planning of their care.

The following is a summary of the comments received and our responses.

*Comment:* Some commenters requested clarification as to the meaning of our statement in the proposed rule that beneficiaries could not ''opt out'' of the model. Others were concerned that this could restrict beneficiary choice. Several commenters expressed an opinion that beneficiaries should be able to opt out of the CJR model if they believed that it might result in a less than optimum outcome.

*Response:* In proposing that beneficiaries are not able to ''opt out'' of the CJR model, we meant that beneficiaries are not able to ''opt out'' of having their care—when furnished in a CJR episode—paid for under the bundled payment methodology. This does not mean that their right to choose or decline otherwise covered Medicare items and services is limited. CJR is a test of a new payment methodology, and as such, it is similar in many respects to other payment methodologies that already exist in Medicare, such as the hospital IPPS. For example, payment under the IPPS is a bundled payment but does not create new coverage limits for services contained within the bundle. This model will test changes to how we pay for care, but like Medicare payment systems, it neither defines nor limits coverage, nor limits beneficiary choices to any specific covered services. Providers may be influenced by the CJR payment model, but in our view this would be similar to how they may be influenced by other payment methodologies in Medicare. In both cases, providers are expected not to treat Medicare beneficiaries differently from other patients based on differences in Medicare payment. Moreover, the safeguards discussed in this final rule exist to ensure that the payment structure does not disadvantage Medicare beneficiaries. We note that within traditional FFS Medicare we do not allow beneficiaries to opt out of any Medicare payment systems as payment systems exist to ensure appropriate payments for similar services across beneficiaries and across providers. Furthermore, because beneficiary cost sharing will be unchanged under this model, it will not have a direct financial effect on beneficiaries and therefore minimizes any impacts on beneficiary freedom of choice.

*Comment:* Commenters questioned whether hospitals should be allowed to maintain lists of preferred providers and suppliers. They expressed many concerns about the tradeoffs between beneficiary choice and the ability of the participant hospital to steer, direct, or compel beneficiaries into certain paths or to certain providers and suppliers. The more common sentiment was that CMS should allow hospitals to clearly identify their clinically integrated, preferred partners and promote these relationships to patients as a way of promoting their care redesign efforts. Commenters expressing this view stated that CMS should allow hospitals to differentiate between preferred and non-preferred PAC providers and suppliers, with hospitals determining the providers and suppliers who were in each category. This situation was described as a ''network'' of preferred providers.

Other commenters believed that hospitals should be required to define criteria for inclusion in a ''preferred network'' based in whole or in part on non-financial criteria such as quality metrics, or that hospitals should define and publish the criteria that they use. Other commenters believed that hospitals should be required to offer the same gainsharing contracts to all willing providers or suppliers. Other

commenters pointed to section 1861(ee)(2)(H) of the Act, which states that hospitals must ''not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and identify any entity to whom the individual is referred in which the hospital has a disclosable financial interest or which has such an interest in the hospital.'' These commenters believe that the Act precludes hospitals from establishing and promoting networks under any circumstances.

Commenters recommended that the Secretary establish minimum criteria such as quality of care, health outcomes, price, accessibility, willingness to work together on evidence-based protocols, and patient experience of care, and that CMS should exercise caution if it permits the recommendation of specific providers, given concerns that the hospital may not have an adequate understanding of the difference between providers or provider types or that the hospital may drive patients to ''low cost'' providers in order to retain a greater share of the savings while putting beneficiaries at clinical risk by potentially stinting on care. However, commenters noted that hospitals must be able to limit the options stated to patients because the hospital will be financially responsible for costs in the episode.

*Response:* We agree that hospitals should be allowed to identify preferred providers and suppliers. We believe, as we stated in our proposed rule, that there are ways to balance beneficiary freedom of choice with the ability of hospitals to leverage efficiencies and cost savings that may occur through the use of certain providers/suppliers. On the one hand, we proposed that hospitals could recommend certain providers/suppliers, including providers/suppliers who are CJR collaborators. On the other hand, we proposed that hospitals could not limit beneficiary choice, must inform beneficiaries of all available providers/suppliers, must inform beneficiaries that their choices are not limited to preferred providers/suppliers, and must inform beneficiaries of the mechanisms by which they may file concerns, complaints or grievances. We do not believe that it is necessary to require hospitals to publicize or standardize their preferred provider/supplier selection criteria or release details of their sharing arrangements, as we believe that our proposal, which we are finalizing in this final rule, sufficiently protects beneficiary access while providing the necessary flexibility to hospitals to leverage their relationships with efficient providers and suppliers.

We believe that allowing hospitals to disclose those providers and suppliers who best contribute to improved efficiency and better outcomes does not limit beneficiary choice, provided that beneficiaries are fully informed of any financial dealings that could create a conflict of interest. We therefore believe that identifying these preferred providers/suppliers is consistent with section 1861(ee)(2)(H) of the Act, as it does not specify or limit qualified providers/suppliers that may provide PAC, and we believe that our requirement that beneficiaries must be notified of financial arrangements is both consistent with and required by that section. We further believe that the proposed requirement to notify beneficiaries of all preferred and non-preferred PAC providers/suppliers, coupled with the requirement to identify CJR collaborators that we are finalizing in this rule, provides beneficiaries with sufficient information to allow them to avoid improper steering or referral.

*Comment:* Commenters expressed concern that if hospitals were allowed to maintain and promote a network of preferred providers/suppliers, additional steps were needed to ensure that beneficiaries had access to the entire spectrum of PAC providers. Some commenters suggested that hospitals should be required to ensure that they have an adequate network of PAC providers and have partnerships with a full range of PAC providers. Some commenters also believed that hospitals should be required to document that the full range of PAC providers was offered, documenting conversations with patients about all treatment options, and requiring that discussions between the patient and unbiased care team members should all be on record.

*Response:* We do not agree with these recommendations from commenters. With respect to the extent of the network, we note that different communities have different assortments of PAC providers/suppliers that meet the unique needs of that community. Requiring a full range of PAC providers/suppliers in a network could disrupt established patterns of care in a manner that we do not intend and is not necessary for success under the model, and thus we decline to adopt such a requirement. With respect to specific documentation requirements suggested by commenters, although we agree with the intent of ensuring that hospitals provide full disclosures to beneficiaries, we do not believe that additional regulatory requirements are necessary as hospitals are best positioned to determine the ways in which they can use their existing medical records and discharge planning to document compliance with all applicable Medicare beneficiary notification requirements, including the requirements we are finalizing in this rule, without creating a new administrative burden, which could be extensive if specific conversations were required to be documented.

*Comment:* Many commenters commented on the timing, content and form of the initial beneficiary notification of the model. Most commenters believed that notification at the point of admission was too late and was not occurring at a time when beneficiaries could process and act on the information. They recommended that notification should be provided at least a week prior to admission or during the individual's consultation with their physician, prior to surgery. A commenter suggested that basic fact sheets should be made available to beneficiaries in physician offices. Another commenter believed that we should require CJR hospitals to meet with prospective beneficiaries prior to admission so that this notification could be delivered and discussed.

With respect to content, some commenters believed that the notification should be highly standardized, based on a standard or model notice created by CMS, or even that CMS should create and provide a single notice to all beneficiaries. Other commenters believed that the notice should reflect specifics of the PAC specific network or of the patient, informing beneficiaries of differences in capacity and patient incurred costs among the various settings or explaining the patient's ability to choose their own PAC provider/supplier, even if the hospital is not satisfied with the quality of the provider/supplier that is chosen. Finally, a commenter believed that the model should be considered to be human experimentation and should follow human subject notice requirements.

With respect to form, several commenters opined that beneficiary notification should be permitted on an electronic basis, with proof of receipt by the beneficiary rather than a paper process that requires a beneficiary's signature.

*Response:* We believed that we had identified the essential elements in our proposed rule, and that any notice that was compliant with those elements would provide sufficient notice to the beneficiary. We acknowledge that this model will be collecting information

about humans as we monitor the impact of this payment model on the quality and efficiency of the delivery of patient care, but we further note that, under the public benefit exemption at 45 CFR 46.101(b)(5), this would qualify for exemption from the HHS human subjects regulatory requirements, and is therefore not required to comply with those requirements. However, we agree with commenters that additional specific details regarding the notice requirements and a model notice will improve the consistency of the notification. We discuss those additional requirements in the following paragraphs and we will incorporate them in a model notice or model notices which we will produce. We will produce a model notice or model notices, or versions of a model notice, that will satisfy our notice requirements for physicians who are CJR collaborators, for PAC providers and suppliers who are involved in a sharing arrangement, and for participant hospitals, who are required to provide beneficiaries with general notice of the CJR model.

With respect to timing, we proposed that beneficiaries should be notified at the point of admission because it is hospitals that are participants in the model, not physicians. We do not agree that the point of admission is too late, noting that the point of admission is when notice of other patient rights regarding the hospital stay are required by Medicare. However, we acknowledge that earlier notification of the beneficiary is desirable. We concur that a beneficiary fact sheet and/or a standard notification form for voluntary distribution in the physician's office would be helpful, and that physicians should be encouraged to explain the model to prospective patients as early as possible. In addition to the model notification forms for hospitals, physicians, and PAC providers/suppliers that we will develop and publish prior to the start of the model, we will consider developing a model fact sheet as we develop educational materials, and we note that participant hospitals are not precluded from developing such fact sheets for the use of their medical staff. Furthermore, we agree that, in the limited case of physicians who have sharing arrangements with hospitals, we are modifying the regulations text from what we proposed to specify that hospitals must include in any physician sharing arrangement a condition under which the collaborating physician—(1) Agrees to notify the patient of the structure of the CJR model; (2) agrees to inform the patient that the physician is participating in a sharing arrangement; and (3) agrees to deliver that information at the time that a decision for surgery is made. We also will modify our proposal in response to concerns that more PAC-specific notice is necessary. In addition to this physician notification requirement, we will require notification of involvement in a sharing arrangement from any other providers and suppliers engaged in a sharing arrangement with a participant hospital, with that notice of involvement to be delivered before the first time a service related to the joint replacement, such as a PAC SNF stay, is furnished to the beneficiary by that entity. However, in response to comments to preserve participant hospitals' flexibility, as we previously discussed we are not finalizing our proposal that these notices would be approved by CMS, but we will instead develop one or more model notices that participant hospitals and others can use.

With respect to form, we agree with commenters that written communication is not limited to paper, and we note that we did not propose a written signature requirement in regulation. We agree that electronic health records may be used to maintain documentary evidence of written communications, and we have not specified a specific mechanism by which proof of beneficiary notification must be maintained.

*Comment:* Commenters were varied in their opinions regarding the requirements for the hospital to identify PAC providers/suppliers at the point of admission and/or the point of discharge planning. Many commenters believed that the hospital should be required to provide a list of all PAC providers. There was a concern that the CJR model may function like ACO networks, where it will be mandatory to tell beneficiaries which providers are in network, but it will not be mandatory to disclose out-of-network options. It was common, but not universal, for commenters to believe that the list could distinguish the providers included within a CJR participant hospital's provider network (preferred) from those not participating in the CJR model (not preferred), that is, which PAC providers are ''collaborators.'' Some commenters believed that financial arrangements should be disclosed, while others believed that non-financial arrangements should also be disclosed. Focusing on the list of collaborators, commenters suggested that the hospital identify all CJR collaborators and should further identify differences between CJR collaborators that may be important to beneficiaries, including such things as their geographic proximity.

*Response:* Noting the wide range of comments, we believe that our proposed rule represents a middle position that adequately balances transparency and beneficiaries' need to know their full range of options with hospitals' desire to inform beneficiaries to which PAC providers/suppliers are most efficient and provide the highest quality care. We believe this is best accomplished by requiring hospitals to provide beneficiaries with a complete list of all PAC providers/suppliers in the area but allowing them to identify ''preferred providers,'' that is, high-quality, efficient providers whom a participant hospital would prefer patients choose, on the basis of internal assessments of quality and cost. Because we recognize that there may be many high quality and efficient PAC providers/suppliers who do not enter into sharing arrangements, we do not believe that a hospital's list of preferred providers/suppliers must include only CJR Collaborators, nor do we believe that all CJR Collaborators must be considered to be preferred providers/suppliers. We do not believe that the details of sharing arrangements need to be disclosed, as those arrangements may be business-sensitive, but we do believe that the existence of any CJR gainsharing or other financial relationship with any physician or PAC provider must be disclosed. We recommend that hospitals be transparent in how preferred providers/suppliers are generally selected, and we note that policies that define the relationships between the participant hospital and the physicians and PAC providers/suppliers in its region must be consistent with applicable law, but we do not believe that the details of hospitals' internal business processes must be disclosed. However we do agree that additional notification as part of discharge planning is important. We will also modify our proposal in response to comments to add a patient-specific financial notification at the point of discharge planning. We will require that a supplementary notification should be made available to beneficiaries, requiring that hospitals must, at the point of discussing PAC options, provide written notification to beneficiaries if the hospital makes any referrals for non-covered services during discharge planning. Specifically, hospitals shall be required to notify beneficiaries of any transfers to a SNF under circumstances in which the SNF stay will not be covered, and also notify the beneficiary of any other referral for PAC that the hospital knows or should

have known will not be covered by Medicare.

*Comment:* Commenters requested that CMS provide additional information about what details must be included in the beneficiary notices, and stated that significant education of hospitals will be required. To promote facility compliance and avoid improper interpretations or incorrect assessments at audit, some commenters urged CMS to completely waive hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services. Other commenters recommended that we provide specific guidance on how to facilitate and operate within partnerships with PAC collaborators (whether a financial or simply a clinical partnership exists) while also complying with existing patient choice requirements. A commenter suggested that hospitals could continue to be required to—(1) Inform the patient or the patient's family of their freedom to choose among participating Medicare providers of post-hospital care services; (2) respect patient and family preferences when they are expressed; (3) present a complete list of qualified providers that are available to the patient; and (4) recommend high quality PAC providers with whom they have relationships (either financial and/or clinical) for the purpose of improving quality, efficiency or continuity of care.

*Response:* We agree that additional guidance may be helpful and believe that, in addition to the discussions we have included in this preamble to our final rule, such information may best be provided as additional detail in the regulation text governing beneficiary notification and supplemented by published guidance and educational materials. We agree with commenters' suggestions of additional details that they believe should be specified in order to promote understanding, consistency and compliance. Therefore, we will modify the beneficiary notice requirements as recommended in comments, to require participant hospitals to—(1) Inform the patient or the patient's family of their freedom to choose among participating Medicare providers/suppliers of post-hospital care services; (2) respect patient and family preferences when they are expressed; and (3) present a complete list of qualified providers/suppliers that are available to the patient. We believe that these requirements were inherent in our proposal to require notice of all qualified providers/suppliers but we acknowledge that the additional details may be helpful.

We do not agree that a waiver of existing discharge planning requirements is necessary, and we discuss the specification of allowable and non-allowable financial arrangements in section III.C.10. of this proposed rule. However, we will also add additional details concerning financial arrangements to our notice requirements in order to protect beneficiaries while ensuring that hospitals, if desired, may recommend ''preferred providers,'' that is, high quality PAC providers/suppliers with whom they have relationships (either financial and/or clinical) for the purpose of improving quality, efficiency, or continuity of care. Specifically, in order to address financial concerns deriving from potential conflicts of interest, we will specify that hospitals and collaborators must disclose the existence of sharing arrangements. In order to protect against situations which might expose beneficiaries to unexpected liability, we will also specify that hospitals must provide written notification of any non-covered services which are recommended or considered as part of discharge planning whenever a hospital knows or should have known that such services are non-covered.

*Comment:* Commenters were concerned that it could be confusing to inform beneficiaries that any participating SNF could provide covered services if the 3-day stay rule was met, but that SNFs meriting 2 stars or less would not be covered under the 3-day waiver provisions. This was believed to be particularly problematic because individual star ratings can change frequently, making it difficult for hospitals to keep up with all current ratings. Commenters inquired whether they could limit the list of PAC providers stated to beneficiaries.

*Response:* We do not agree that this is overly confusing as beneficiaries already understand that there are statutes and regulations that define the circumstances under which SNF stays are covered, for example, following a 3-day hospital stay. Moreover, we have stated that it is essential for beneficiary choice to ensure that beneficiaries are informed of all covered opportunities available to them, including PAC providers/suppliers considered by the hospital to be preferred as well as non-preferred. Since stays in SNFs that do not meet the conditions of the 3-day waiver would be covered by Medicare if they met the existing conditions for coverage (that is, the beneficiary has a qualifying 3-day hospital stay), these SNFs still must be included in any complete list of PAC providers. Providing the complete list is necessary to meet the requirements of section 1861(ee)(2)(H) of the Act, a requirement which we believe promotes beneficiary choice. However we do note that the star rating may be critical for the beneficiary to determine liability in the event that a beneficiary is discharged with less than a 3-day stay. We had proposed that cost-sharing and quality information must be provided to beneficiaries where applicable and we agree with commenters who recommended that additional information about beneficiary liability could be provided. Therefore, we are modifying our requirement to notify the beneficiary of all covered PAC options by adding that this list of PAC options stated as part of discharge planning must be accompanied by a written statement that identifies any non-covered services to which the beneficiary may be referred. Specifically, in the event that the patient is discharged prior to completing a 3-day stay, the hospital will be required to clearly identify, in writing, any 1 or 2 star SNFs on the complete list of PAC providers provided to the beneficiary. In the event of a discharge prior to a 3-day stay, the list must also include a statement that the named beneficiary, having not completed a 3-day stay in the acute care hospital, would be entirely financially responsible for a stay at any of those 1 or 2 star SNFs.

*Final Decision:* After consideration of the public comments received, we are finalizing our proposal to require that hospitals in the CJR model notify beneficiaries of the requirements surrounding the model at the point of admission to the hospital and we are modifying our proposal to add additional detail to the content, timing and form of our notification requirements in response to comments, as specified in this paragraph. We will continue to require participant hospitals to provide beneficiaries on admission with a general notice of the existence of the model and of certain beneficiary rights. We are requiring that, as discussed in the preamble to the proposed rule, participant hospitals must require as a condition of any sharing arrangement that the collaborators must notify beneficiaries of the existence of a sharing arrangement. We are modifying our regulations to specify that, in the case of physicians, this notification must occur at the point of the decision to proceed to surgery, or, in the case of other collaborators, prior to the furnishing of the first service provided by the

collaborator that is related to the joint replacement. We additionally are finalizing with modification our PAC notification requirements, specifying that participant hospitals as part of discharge planning must inform beneficiaries of all Medicare participating PAC providers/suppliers in an area but may identify those providers/suppliers that the hospital considers to be preferred. To increase beneficiary awareness we are specifying that the participant hospital must also as part of this specific second notice inform the beneficiary of providers/suppliers with whom a sharing arrangement exists. We are further modifying the notification requirements to require participant hospitals to reference the most recently published CMS list of SNFs which qualify for the waiver of the 3-day rule. This modification is to specifically notify beneficiaries of their liability should they be discharged upon a less-than-3-day stay to a SNF that does not qualify for the waiver that we are finalizing for this model, and to notify the beneficiary of possible beneficiary liability if the hospital recommends or refers the beneficiary to any other services, which it knows or should have known to be non-covered services under Medicare. This latter notice is in addition to any ABN or other hospital notice of noncoverage that may be required under existing regulations.

3. Monitoring for Access to Care

Given that participant hospitals would receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. We will publish these data as part of the model evaluation to promote transparency and an understanding of the model's effects. We also proposed to continue to review and audit hospitals if we had reason to believe that they are compromising beneficiary access to care. For example, where claims analysis indicates an unusual pattern of referral to regional hospitals located outside of the model catchment area or a clinically unexplained increase or decrease in joint replacement surgery rates.

The following is a summary of the comments received on monitoring for access to care, and our responses.

*Comment:* Many commenters reported concerns related to ways in which the payment structure might adversely impact the services that were available to beneficiaries. Commenters also suggested a number of approaches to mitigate those general risks, such as increased risk adjustment, and increased quality measures in order to improve beneficiary protections. These comments are addressed in the preamble sections most closely concerned with the individual topics.

Commenters raised a number of questions about determinations of medical necessity and their effect on access to care. A commenter, quoting our proposed rule in which we stated that gainsharing payments and alignment of payments must not induce collaborators to limit medically necessary services, requested that we articulate who will decide what is medically necessary and how this determination would be made. That commenter recommended that we encourage the use of treatment protocols based on objective criteria. Other commenters urged us to require CJR participant hospitals to demonstrate that they have appropriateness criteria in place to assess beneficiary need for joint replacement.

Commenters had two competing concerns. First, they were concerned that the bundled payment created a risk of patient ''dumping,'' or inappropriately referring patients to other providers based on financial considerations. They were concerned that surgeons/hospitals will avoid complex/sicker patients not only to avoid the losses associated with expensive cases but also to avoid cases at risk for readmission. Similarly, they stated that hospitals will avoid lower socioeconomic patients unless there is a socioeconomic risk adjustment. Commenters suggested that these risks could be mitigated by adding specific, separate penalties for withholding care or steering patients inappropriately or rejecting patients entirely. These penalties should progress up to and include termination from Medicare.

Second, commenters identified a risk of overutilization. These commenters believed that some physicians and hospitals will provide services to healthier patients who could benefit from less invasive treatments in order to improve their metrics, or increase volume to account for lost revenue, or treat healthier patients, which will result in adjustments to a hospital's patient mix. A commenter asserted that both influences are already in effect, with considerable overutilization of LEJR (based on regional variation) and also with some studies suggesting that ''only 1 in 10 patients needing LEJR are getting it.''

Commenters also recommended other steps in addition to a general recommendation for an appropriateness (medical necessity) measure to gauge the appropriateness of care at the beginning of the episode. It was for this reason that commenters urged us to require CJR participant hospitals to demonstrate that they have appropriateness criteria in place to assess beneficiary need for joint replacement. Commenters urged CMS to monitor changes in utilization patterns and case mix as part of the evaluation, and to generally monitor whether barriers to patient access develop in MSAs participating in the CJR program, and to make necessary alterations to the model if complicated hip/knee replacement cases are found to be underserved.

*Response:* We acknowledge that overutilization and underutilization are both potential issues related to access. We note that the usual tools employed by CMS to monitor and prevent overutilization all apply to the services delivered within the CJR model. These tools include data analysis, the process of tracking patterns of utilization and trends in the delivery of care, and medical review, a clinical audit process by which we verify that services paid by Medicare were reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. We believe that these tools as employed by the MACs and by the QIOs will be sufficient to check for the medical necessity of CJR services. We do not believe that it is necessary to impose a requirement that hospitals maintain specific appropriateness criteria. We note that there are a wide variety of criteria developed by national healthcare organizations, including providers and payers, and that a process that is appropriate for a large facility with many community physicians might not be workable in a smaller facility with a single LEJR surgeon. With respect to underutilization, we agree that it is important for us to monitor changes in utilization patterns and case mix, and to generally monitor whether barriers to patient access develop in MSAs participating in the CJR model. We note that this is encompassed by the evaluation process for the model, so we will be able to make necessary alterations to the model if complicated cases are found to be underserved. However, we do not at this time believe that specific requirements for medical necessity or utilization review are necessary, beyond those broad requirements which are set by the CoPs,

such as those at § 482.30. We believe that the existing influences of reputation, care guidelines, QIO review, Joint Commission review, quality metrics, and our retrospective model evaluation are sufficient to ensure that beneficiary access to care is not impeded.

We also agree with commenters that additional specific regulatory detail should be added to address the consequences of systemic underutilization. We proposed that participant hospitals would not be eligible for reconciliation payments if those payments are associated with actions that threaten beneficiary health, and we note that systemic instances of under-delivery of care threaten that health and therefore constitute a reason to withhold reconciliation payments. We also note that we have the authority to revoke provider enrollment in the Medicare program for cause, such as providing substandard care that places beneficiaries at risk that, is, by under-delivering care. As an intermediate step, we further note that we have additional options, such as requiring additional actions under a corrective action plan in order to avoid revocation. However, we reiterate that we do not believe such aggressive measures are necessary, as we believe that such concerns as reputation and patient outcomes provide sufficient motivation for most providers/suppliers.

*Comment:* Commenters also identified concerns about inappropriate limitations of access to certain services due to network restrictions for beneficiaries who are appropriately undergoing a joint replacement. Some commenters believed that the current CJR proposal has the potential consequence of encouraging hospitals to select only the most ''efficient'' or ''cost effective'' orthopedic surgeon to enter into sharing arrangements or to continue having admitting privileges. Hospitals might de-credential or restrict surgeons who treat expensive patients. Similar concerns exist for PAC providers; the model might encourage hospitals to limit access to small providers/suppliers, or encourage hospitals to buy small PAC providers and even physician practices. While integrated systems may lead to more coordinated care, consolidation may also lead to price increases and diminished quality as competition is reduced. Commenters believed that CMS should introduce a prohibition of any practice of excluding ''less efficient'' or ''less cost effective'' surgeons or PACs. Other commenters suggested that we should monitor activities involving distribution of payments to guard against unfair business practices and to promote a fair and equitable distribution of savings for all providers who are involved as collaborators.

*Response:* While we recognize the concerns that higher quality is sometimes at odds with lower cost, we note that the purpose of this model is to encourage more efficient delivery of high quality care, that is, to reduce cost while maintaining or increasing quality. We believe that such factors as reputation and peer-reviewed practice guidelines work to ensure that hospitals and physicians will continue to provide quality services. We also believe that the antitrust laws help to prevent anti-competitive practices in the maintenance of hospital networks, allowing competition between network providers to promote high quality outcomes. While we believe that antitrust laws, anti-kickback provisions and other existing laws and regulations may help deter the business practices which concerned commenters, we agree that additional monitoring is prudent and will therefore monitor sharing arrangements and beneficiary and provider/supplier comments for any evidence of anticompetitive behavior.

*Comment:* In addition to the previous commenters' concerns about opportunities for participant hospitals to restrict beneficiary access to specific providers, commenters were also concerned about opportunities for the under-delivery of care by providers the beneficiary did access, that is, underdelivery of care by the participant hospitals and their collaborators. This practice is often referred to as ''stinting.'' Commenters were concerned that the CJR model does not represent a balanced approach to improve quality while reducing cost. Overall, they believed that the use of Medicare spending per beneficiary scores as a key indicator will drive hospitals to low cost care at the expense of quality. Specific concerns were that patients may be directed away from more expensive PAC options (IRFs or SNFs, for example), it will discourage extensive therapy in the PAC environment even when warranted, less attention will be paid to such positive factors as prevention (for example, falls), pain management and overall outcomes, and readmissions may be avoided even when necessary. A commenter was also concerned that beneficiaries may be forced to attend in-network facilities rather than out-of-network facilities near their homes. To mitigate these concerns, commenters recommended that controls be put in place to ensure that sicker patients receive LEJR and appropriate higher intensity PAC, to ensure that collaborators do not reduce or limit medically necessary services to any beneficiary, and to ensure that physicians continue to select the devices, supplies and treatments that are in the best interest of the patients. They recommended a pre-model hospital review, that hospitals have the ability to deliver, or contract for, evidence-based care for the entire bundle of services, including the capacity to provide all levels of rehabilitation services, including people with disabilities or who may need intensive rehabilitation services and/or community supports. Finally, several commenters recommended that alternative payment options should be considered for otherwise expensive environments such as the IRF, SNF, and, in the case of outpatient surgery, the outpatient hospital or ambulatory surgical center.

*Response:* We agree that commenters have accurately described possible risks, and we note that similar risks are inherent in all bundled payment models and systems. For example, commenters expressed similar concerns when DRGs were introduced in 1985, yet DRGs are now used in the established IPPS. After 30 years of use, we have not reported any evaluations establishing that the economic pressures to create efficiencies have compromised beneficiary care, so we do not expect different results with this model. Nonetheless, we agree that monitoring is necessary in order to further reduce these potential risks. However, we have consistently found that those traditional authorities available to the Secretary, previously discussed in their role to prevent the use of limited networks to avoid the delivery of necessary services, are adequate to provide a counterbalance to the economic incentives that could drive underdelivery of care. Therefore, we believe that we must use our existing oversight authority to monitor the risks of this payment model, just as we monitor the various risks inherent in all payment models and systems, but we do not believe that new controls are necessary which require specific incorporation into regulation, other than those which we proposed and we have now modified in response to comments.

We do not believe that the additional controls are necessary because we have a number of established mechanisms by which we will monitor for evidence of the underdelivery of care, and by which we can react to and mitigate any identified problems. We will be monitoring data in the process of calculating quality metrics, and we have several reporting mechanisms, such as

1–800–MEDICARE. We monitor the quality of hospitals stays and surgical procedures through the QIO, we routinely review medical records in our claims audits, and we specifically investigate outcomes as part of our evaluations of demonstrations and payment and service delivery models. All of these processes create opportunities to identify potentially non-compliant providers/suppliers. Providers/suppliers who are investigated and found to be inappropriately denying care or diverting patients may be sanctioned using our existing authority, with penalties that may include participant hospital ineligibility for reconciliation payments, revocation from the Medicare program if patients are placed at risk by substandard care, or other applicable administrative actions.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to apply our existing authority to monitor for overutilization and underutilization of care under the CJR model. We are modifying our proposed policies for reconciliation payments at § 510.410 to allow us to determine that a participant hospital is ineligible to receive or retain a reconciliation payment if the payment is found to be based in part on savings resulting from an inappropriate and systemic underdelivery of care.

4. Monitoring for Quality of Care

*Monitoring General Quality of Care:* As we noted previously, in any payment system that promotes efficiencies of care delivery there may be opportunities to direct patients away from more expensive services at the expense of outcomes and quality. We believed that professionalism, the quality measures in the model, and clinical standards can be effective in preventing beneficiaries from being denied medically necessary care in the inpatient setting and in PAC settings during the 90 days post-discharge. Accordingly, the potential for the denial of medically necessary care within the CJR model will not be greater than that which currently exists under IPPS. However, we also believe that we have the authority and responsibility to audit the medical records and claims of participating hospitals and their CJR collaborators in order to ensure that beneficiaries receive medically necessary services. We may also monitor agreements between participant hospitals and their CJR collaborators to ensure that such agreements do not result in the denial of medically necessary care or other program or patient abuse. We invited public comment on whether there are elements of the CJR model that would require additional beneficiary protection for the appropriate delivery of inpatient care, and if so, what types of monitoring or safeguards would be most appropriate.

The following is a summary of the comments received on monitoring for quality of care, and our responses.

*Comment:* Several commenters stated that CMS should ensure the safety and cost effectiveness of surgical implants used in the CJR model and that CMS should require that evidence-based purchasing be required in the CJR model. As these commenters were concerned that hospitals will avoid high cost devices, they urged CMS to put controls in place that protect patients against wholesale changes in device offerings of providers. A commenter suggested that we should consider prohibiting gainsharing altogether when tied to the use of less expensive and lower-utility devices but in any event that participating hospitals should be carefully monitored for the appropriateness of device choice for individual patients and surgeons.

*Response:* We note that the CJR model is built around an inpatient admission. Under the IPPS, the cost of the device is already bundled into the payment for the hospital admission. Therefore, hospitals have long had incentives to use less expensive and lower utility devices as a way of maximizing their profit under IPPS. However, we have not identified any problems with the inappropriate use of inexpensive devices, so we believe that existing considerations, such as hospital and physician reputation, clinical standards, and incentives to maintain high quality outcomes, have been successful in driving the appropriate selection of devices. We do not believe that there are any significant new incentives to inappropriately use lower quality devices as the device remains packaged in the IPPS payment bundle. We believe that ongoing monitoring of the quality of devices and the selection of specific devices for specific beneficiaries is appropriate, but, given the success of our over 30 year experience with IPPS, we do not believe that additional programs need to be defined in regulation. However, we do expect that the focus on shared decision making and physician leadership, described in the following discussions, will further reduce any beneficiary risk.

*Comment:* Commenters provided their views about the role of quality metrics in ensuring the quality of care as a counter to economic pressures. They expressed concerns about the design of the metrics, concerns that are discussed in the quality section of this rule, but they also expressed concerns that the quality metrics were not adequate protection against the delivery of poor quality care. Commenters were concerned that the proposed model does not include enough safeguards to substantially improve the care experience, and that reference to quality and outcomes were inadequately defined. Some commenters were also concerned that measurements were hospital-centric, with inadequate consideration of tools that assess such measures as patient functional status, a component that they believed tied closely to protections that promote improved beneficiary care. Commenters proposed that quality metrics should include functional requirements, pain management and patient experience, patient reported outcomes and other measures of the outcomes of the post-acute care treatment. They also opined that the public reporting of quality measures would help empower consumers to make informed decisions.

*Response:* We agree that there are opportunities to better employ quality metrics. However, we note that obstacles exist not only in defining new measures but in implementing mechanisms to report and asses those metrics without creating undue administrative burdens or provider technological challenges. For example, we note that it will take time to collect and validate data required under the IMPACT Act but once that has occurred it will create opportunities for potentially better metrics. Therefore, we thank commenters for their suggestions and note that while we are finalizing a set of quality metrics for this year, the methodology by which this model is being phased in, with gradually increasing economic incentives, gives us an opportunity to continue to evaluate the use of quality metrics and modify them through future rulemaking if better metrics emerge.

*Final Decision:* After consideration of the public comments we received, we are finalizing the proposal to use our existing authority to audit claims and services, to use the QIO to assess for quality issues, to use our authority to investigate allegations of patient harm, and to monitor the impact of the quality metrics that we are finalizing.

*Monitoring PAC Quality of Care.* With respect to PAC, we believed that requiring participating hospitals to engage patients in shared decision making is the most important safeguard to prevent inappropriate recommendations of lower cost care, and we stated in the preamble that such a requirement can be best effected by requiring hospitals to make this a

condition of any sharing arrangements with practitioners who perform these procedures, although we did not propose any regulations text. Additional deterrents are created by the financial accountability of the 90-day bundle, which is sufficiently long that it encourages the provision of high-quality care to avoid the risk of complications and readmissions, which would typically occur within that time period. Physician patterns of practice are also constrained by clinical standards of care, and we believe that the risk associated with deviations from those standards provides further deterrence to compromising care.

We believe that these safeguards are all enhanced by beneficiary knowledge and engagement. As we discussed in the section on beneficiary notification, we proposed to require that participant hospitals must, as part of discharge planning, account for potential financial bias by providing patients with a complete list of all available PAC options in the service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and when applicable). We expect that the treating surgeons or other treating practitioners, such as physiatrists, will continue to identify and discuss all medically appropriate options with the beneficiary and that hospitals will discuss the various facilities and providers who are available to meet the clinically identified needs. These proposed requirements for CJR participant hospitals would supplement the existing discharge planning requirements under the hospital CoPs. We also specifically note that neither the CoPs nor this proposed transparency requirement preclude hospitals from recommending preferred providers within the constraints created by current law, as coordination of care and optimization of care are important factors for successful participation in this model. We invited comment on this proposal, including additional opportunities to ensure high quality care.

The following is a summary of the comments received regarding provisions to ensure quality during the delivery of PAC services, and our accompanying responses.

*Comment:* Commenters strongly advocated for the need to encourage shared decision making as a methodology for ensuring that beneficiaries are provided PAC options of the highest quality. The comments consistently followed several themes. Numerous commenters were concerned about the role of the physician/surgeon in the CJR. Some commenters were concerned that physicians are marginalized by placing all economic power with the hospital, and that this will disrupt the physician-patient relationship. These commenters were also concerned that the model fails to recognize the vital importance of the physician's role in healthcare, that the episode is in fact generated because of the orthopedic physician's care for the beneficiary months and sometimes years prior to the LEJR surgical event. These commenters believe that it is the physician/surgeon who drives the care and that this should be incorporated into the model. Conversely, commenters were concerned that hospitals should not be allowed to coordinate and manage care as that represents a conflict of interest since they are the entity that is financially responsible for excess spending during the episode.

*Response:* We agree that the physician/surgeon is critical to the CJR model and that this is incorporated into the concept of shared decision making. As a practical matter, patients place considerable trust in the advice of their physicians, such that almost all medical care is physician-directed even when it is delivered by many coordinated entities. This physician direction is fundamental to the design of most Medicare programs and models, including the CJR model. Although the economic effects of the CJR model are borne by the hospital, considerable economic power resides with the beneficiary and the physician due to the strength of the established doctor-patient relationship. In our proposed rule we repeatedly emphasized the principle of beneficiary freedom of choice, the right to choose any care options and for the fact that Medicare continues to covers all medically necessary Medicare benefits. It is the beneficiary's selection of specific medically necessary options that determines the composition of the episode, because the episode is composed only of services the beneficiary consents to receive and is not impacted by the services that the beneficiary declines. Under the concept of shared decision making, the beneficiary retains that ultimate right to accept or request desired services and refuse services that are not desired. This is a significant economic power. Meanwhile, the physician is responsible for advising the beneficiary as to whether a particular choice is medically necessary and, as a corollary, for advising the patient as to the most medically appropriate and medically beneficial options. This also gives the physician considerable economic power and places him or her in the position, together with the beneficiary, of driving the actual care. The hospital, although it is the participant in the CJR model that is directly tied to the economic incentives, is therefore limited by the additional economic power held by the beneficiary, who holds the final choice with respect to all care, and the economic power held by the physician, who is the primary driver of care through his recommendations to the beneficiary in accordance with the special doctor-patient relationship. These checks and balances are a major mechanism to mitigate against any potential hospital conflict of interest created by the payment bundle.

*Comment:* Commenters proposed numerous and diverse requirements that they wanted us to consider imposing on the CJR decision making process that steers patients into specific PAC settings and services. On the one hand there were some requests for general guidance of what is and is not acceptable in discussions with the beneficiary. A commenter stated that our current proposal does not address the role of the patient in the process, and does not propose methods to empower patients to seek out the highest quality joint care. On the other hand there were numerous recommendations to require certain specific elements in the decision making process. A commenter suggested that we require shared care planning, a concept that includes collaborative provider-patient goal-setting, decision making, and monitoring through the use of documented, completed individualized care plans. Another commenter suggested the inclusion of advance care planning, an opportunity for thorough discussion of patients' desires relative to care options if, following the procedure, they are unable to convey those desires. A commenter recommended a requirement that hospitals create patient family advisory councils or other similar organizations in order to promote the patient perspective in discussions of episode design and care coordination, and suggested that this should include family members if desired by the patient. Commenters advised CMS to ensure that planning is initiated with the primary care physician or surgeon before admission and is coordinated with the pre-admission process conducted by the hospital, and that appropriate standards of care should be a key characteristic of these processes.

*Response:* We recognize that the concept of shared decision making is a complex process, with many permutations based on the needs of the

patient, the availability of resources, and the nature of the individual doctor-patient relationship for each specific case. Therefore, we recognize the importance of shared decision making as previously described, but we defer from specifying other elements that must be included as components of the decision making process. We believe there are many acceptable ways to engage the beneficiary and that, just as different commenters offered different techniques that they have found to be helpful, different hospitals with their unique characteristics will similarly identify and implement the programs that best serve to engage their patient population.

*Comment:* Commenters proposed modifications to the decision making process, as well as recommending different technical systems that they believed should be required by participant hospitals. Some commenters recommended that the hospital should document the use of evidence-based clinical practice guidelines and evidence-based decision aids for shared decision making, and that hospitals should be required to have specific systems in place to coordinate all providers involved in the episode of care, track quality measures, manage medical complications, coordinate with community services to foster the patient's independence and implement evidence-based shared decision making with patients. However, other commenters emphasized the need for technical inclusiveness. A commenter encouraged us to enable providers to participate in these models as collaborators without requiring major investments in infrastructure and electronic health records. Another commenter proposed that patients should not select providers but should select physician-led teams in which a pre-organized slate of providers would collaborate to deliver the necessary portfolio of care.

*Response:* We do not believe that pre-formed teams of PAC providers linked to a single physician would be consistent with beneficiary free choice if beneficiaries were restricted to providers in that specific team. Beyond that, we note that there are many modes of decision making and that different modes may be preferred by different provider groups under different circumstances. We do not believe that a single approach or a single technical solution will meet the needs of the diversity of participant hospitals and patient and provider populations who will be engaged in providing services under this model. For this reason we do not elect to further define mandatory approaches to decision making.

*Comment:* Similar to commenters' concerns regarding additional monitoring to ensure that providers did not limit access to PAC services (''stinting''), commenters also expressed concerns that specific monitoring would be necessary to ensure that those PAC services provided to beneficiaries were not subject to restrictions that adversely impacted their quality. Some commenters recommended that we establish basic requirements for care coordination and competencies that must be met, independent of payment and measurement. Their rationale was that certain functions, such as discharge planning, are so integral to care coordination that requiring them should be routine for entities that aspire to coordinate care well. Specifically, participating hospitals should be required to have clearly documented clinical care models, care and transition plans including shared decision making tools and coordination with community supports, and protocols for documenting discharge planning and PAC coordination and supports.

Other recommended controls included a requirement that any and all documents used by the hospital during discharge planning must be submitted to (not approved by) CMS, a requirement that any agreement between hospitals and PAC providers should be submitted to (not approved by) CMS, and that CMS should do a random sample audit of these agreements to ensure they comply with current regulations. A commenter recommended that CMS make available to the public the amount hospitals earn from reconciliation payments for a performance year, while another recommended that we should do random face to face interviews post discharge to determine if the patient was steered to a particular provider if such interviews warranted based on changes in utilization rates or if we identify inappropriate or concerning sharing arrangements between a hospital and a PAC provider.

Other commenters wanted us to underscore in the final rule that hospital utilization review committees and physicians who sign discharge orders remain fully accountable to make the determination that a patient discharge is medically appropriate. A commenter believed that part of the discharge process should include an independent determination that medical resources and care required by each beneficiary are available in an available PAC setting.

*Response:* We agree with commenters that monitoring is essential to protect against practices that might reduce the quality of PAC services. We believe that monitoring for quality is accomplished at the population level through the monitoring for access to the appropriate level and quantity of PAC services, a process that we discussed earlier with respect to underutilization of services. We also believe that the practice of shared decision making, the reliance on the medical direction of the physician, the monitoring of quality metrics, the complaint and oversight opportunities through 1–800–MEDICARE and the QIO, and the use of care coordination all cooperate to ensure the quality of individual services delivered to individual beneficiaries.

With respect to comments that we establish basic requirements for care coordination or require specific documentation of care coordination procedures, we agree with commenters that activities such as discharge planning are integral to care coordination. However, we note that it is one function of state agencies and accrediting organizations to ensure that discharge planning is effectively addressed, and that their applications of the CoPs are updated as necessary to establish appropriate standards. We note that CMS has recently proposed updated discharge planning requirements for hospitals through proposed changes to the hospital CoPs.

We do not believe that new requirements, such as CMS receipt of discharge planning documents or public posting of amounts involved in gainsharing, are necessary to ensure appropriate post discharge care. We note that, with the exception of waivers discussed in section III.C.11. of this final rule, all other Medicare rules for coverage and payment continue to apply. However, as discussed elsewhere in this section of this final rule, we have modified proposed § 510.500 to require additional disclosure of CJR sharing arrangements with PAC providers to CMS. Therefore, we believe that sufficient controls are in place to allow us to ensure the quality of the PAC services without requiring additional public disclosure or CMS approval.

We also note that whereas both utilization review activities and discharge planning are required by the hospital CoPs, a review of the appropriateness of post-discharge services is not an activity currently undertaken by hospitals. We agree that the ultimate direction for the care of the patient lies with the physician and patient, and claims for services are subject to appropriate validation and

review for coverage and medical necessity. We do not believe that at this time it is necessary or appropriate to require a medical necessity review of every PAC decision under the model. First, we note that such a requirement would create a significant administrative burden that would need to be balanced against the potential benefits. Second, we believe that the hospital and its PAC providers must already comply with existing federal and state requirements to respect beneficiary wishes and follow physician direction. Third, we have noted the opportunities available to the beneficiary, such as the 1–800–MEDICARE line, to raise quality concerns associated with the episode of care.

*Comment:* Commenters offered other suggestions and observations on opportunities to improve beneficiary protections that ensure the delivery of quality care. Several commenters suggested that CMS should require a ''second opinion'' process whereby a concerned consumer can seek an independent medical opinion concerning a PAC plan. Other commenters opined that we should provide appeal rights to any Medicare beneficiary subject to the CJR model, comparable to those appeal rights available to Medicare Advantage enrollees, in order to protect against ''adverse care'' decisions. Still other commenters encouraged us to inform beneficiaries of the hotlines available to convey grievances on care at each level of service during the episode, to develop training for 1–800–MEDICARE call center staff to identify and flag potential care reductions or inappropriate steering in this model, to ensure that the State Health Insurance Assistance Programs (SHIPs) are appropriately trained and engaged as the final model is implemented, and to highly publicize outlets where consumers can provide positive or negative feedback, such as 1–800–MEDICARE and the contact information for the local QIO. A commenter proposed that we consider establishing an independent ombudsman program.

*Response:* We do not believe that a second opinion program or special appeal rights are necessary. First, as we have previously discussed, there are numerous processes in place to protect beneficiary choice. The beneficiary retains all rights to choose the provider/supplier for medically necessary covered services. The beneficiary retains the benefits of the doctor-patient relationship, with additional notification of any sharing arrangement that could create a potential conflict of interest. In the event that the beneficiary is stated with a notice of non-coverage for continuing services, such as a continued stay in a participant hospital or a SNF, the beneficiary has access to the existing expedited review process. The beneficiary may also voice concerns or grievances, such as to the QIO or through 1–800–MEDICARE. We also do not agree with the need to establish a dedicated ombudsman, given the existence not only of the appeal process but also of the existing office of the Ombudsman. However, we agree that it would be beneficial to distribute educational materials to ensure that beneficiaries can take advantage of the support available at 1–800–MEDICARE, at the SHIP, and especially at the QIO, and we will consider developing such materials in the future.

*Final Decision:* After consideration of the public comments we received, we are finalizing our regulations as proposed and are not creating additional requirements for discharge planning or care coordination specific to the CJR model, beyond the previously identified requirements that hospitals must provide a complete list of PAC providers and that CJR collaborators must provide notice that they are participating in a CJR sharing arrangement with the hospital.

5. Monitoring for Delayed Care

This model is based in part on an incentive for hospitals to create efficiencies in the delivery of care within a 90-day episode following the joint replacement surgery. Theoretically this could create incentives for hospitals and other CJR collaborators involved in any CJR sharing arrangements to delay services until after that window has closed.

We believe that existing Medicare safeguards are sufficient to protect beneficiaries. First, our experience with other bundled payments such as the BPCI initiative has shown that providers focus on appropriate care first and efficiencies only when those efficiencies can be obtained in the setting of appropriate care. We believe that a 90-day post-discharge episode will sufficiently minimize the risk that services furnished in relation to the beneficiary's LEJR procedure will be necessary beyond the end of the episode duration. To ensure that the length of the episode duration sufficiently minimizes the risk that any LEJR related care will not exceed the time established for the episode, we proposed to establish a 90-day post-discharge duration. We believe that participant hospitals would be unlikely to postpone services beyond a 90-day period because the consequences of delaying care beyond this long episode duration would be contrary to usual standards of care.

However, we also note that additional monitoring would occur as a function of the payment model. We have proposed as part of the payment definition (see section III.C. of the proposed rule) that certain post-episode payments occurring in the 30-day window subsequent to the end of the 90-day episode would be counted as an adjustment against savings. We believe that the inclusion of this payment adjustment would create an additional deterrent to delaying care beyond the episode duration. In addition, the data collection and calculations used to determine this adjustment provide a mechanism to check if providers are inappropriately delaying care. Finally, we note that the proposed quality measures create additional safeguards as they are used to monitor and influence hospital clinical care at the institutional level. We invited public comment on our proposed requirements for notification of beneficiaries and our proposed methods for monitoring participants' actions and ensuring compliance as well as- on other methods to ensure that beneficiaries receive high quality, clinically appropriate care.

The following is a summary of the comments received and our responses.

*Comment:* Commenters provided numerous suggestions and observations on the processes by which we will monitor the model in order to ensure that the beneficiary is fully protected against unintended consequences. Commenters were in agreement with our intent to monitor for unexpected changes in the delivery of care, but several commenters believed that additional explanation would be helpful. A commenter believes that it was not clear what would constitute an inappropriate change in delivered services, particularly in light of the fact that the intent of this model is to promote change. Other commenters believe that, just as more definition was needed around the concept of inappropriate change, more definition was needed to define the contractors who would audit for those changes. A commenter requested that CMS build into the CJR model checks and balances to assess the CJR patient's care throughout the duration of the episode and extending for four months beyond the end of the episode. Another commenter suggested that a similarly structured auditing system should be established to monitor CJR participants' care management processes and compliance with the patient-centered

care planning expected in the model, with audits conducted by an outside party in the early stages of the new model and periodically thereafter.

*Response:* We understand that commenters would like additional definition surrounding inappropriate changes. We consider changes in patterns of care to be inappropriate when they do not improve the quality and efficiency of care delivered to Medicare beneficiaries, or when they occur in violation of statute, regulation, or guidance. This would include, for example, practices that prevent potentially higher-cost patients from receiving services, reduce the delivery of medically necessary services, limit beneficiary choices between equally valued options, increase or fail to reduce waste, or maximize reimbursement at the expense of the beneficiary. However we do not believe that specific examples must be identified in regulation. Rather we believe that the regulation should define the general principles under which the beneficiary must be protected and the authorities under which monitoring will take place, and we have so defined these principles in § 510.410. For example, we stated that action that threatens the health or safety of patients and actions to avoid at risk Medicare beneficiaries are prohibited actions, so we would consider changes that result from ''stinting'' (threatening the health of patients) and ''patient dumping'' (avoiding at risk beneficiaries) to represent inappropriate change. We also expect to interact with both providers and our contractors over the course of this model, to refine and clarify our educational materials and, when necessary, our regulations or guidance. We note that although we defined the types of inappropriate changes in § 510.410, we do not believe that it is necessary to define through regulation the specific contractors who will be responsible for monitoring this aspect of the program. We have numerous contractors who have the authority and scope to perform this work, and we will use our usual contracting authorities to assign any necessary tasks during the life of the model. We also note that we previously discussed that we did not believe that additional auditing of providers' discharge planning and care coordination activities was necessary. Given that we do not believe that special audits are necessary to ensure the quality of PAC services to a specific beneficiary, we similarly do not believe that audits of care coordination are necessary to monitor the quality of care delivered to the population as a whole. We believe that the financial incentives of the model promote increased care coordination, a process that will increase the timeliness of interventions and reduce opportunities for delays in care.

*Comment:* Commenters had specific comments about the extent of post-episode monitoring and about monitoring in general, which is necessary to track for the occurrence of instances of delays in the delivery of care.

Commenters suggested that post-episode monitoring should be extended for at least 3 to 6 months after the end of the bundle period or even 5 or more years in order to include the late effects of suboptimal implant selection. As part of PAC monitoring, commenters acknowledged that CMS proposed to look at changes in referral patterns as a result of the model, but also believed that we should evaluate the impact that the model may have on the availability of services in a market.

With respect to monitoring in general, commenters requested that we should be more transparent about monitoring. Specific recommendations were that we should track readmission rates, complication rates, ER visits, observation stays, length-of-stay, changes in patient function, and patient experience, gap between discharge and first PAC use and between discharge and physician follow-up visit, days lapsed between discharge from the hospital to the first PAC use, and days lapsed between hospital discharge and the first physician visit. Some providers also requested that we should incorporate information from/related to reporting requirements of the IMPACT Act into functional monitoring. Commenters also believed that we should perform some baseline monitoring, looking at case mix before and after CJR implementation as well as the rates of joint replacement in MSAs included in the CJR model and MSAs excluded from the model.

*Response:* We acknowledge the validity of these recommendations and thank commenters for their suggestions. With respect to prolonged monitoring for long-term consequences related to device selection, we agree that monitoring of this sort is of interest in optimizing long-term outcomes. However, we note that devices have long been included in IPPS inpatient bundles. Thus any risks associated with low cost device selection are not specific to the CJR. We also do not believe that the policy changes necessary to respond to any findings based on sub-optimal device selection would be limited to this model. Furthermore, we note that we would not expect on a clinical basis for any effects of low-cost low-quality devices to become apparent for many years. Therefore monitoring for this impact would require (1) additional years that are at least equally as long as the model duration itself in order to detect quality and cost effects; and (2) similar analysis of the impact of devices provided under IPPS but outside the model. This further underscores the difficulty of including this analysis as a component of the model and suggests that, if such a study is undertaken, it should be a separate study of the impact of device selection both within and outside of the CJR model. On the other hand, we believe that the other measures suggested are all reasonable metrics by which program effects can be monitored. We will consider whether we should incorporate some of all of these approaches in our arrangements with our monitoring and evaluation contractors.

*Comment:* Some commenters questioned the manner in which existing or potential medical review and audit programs would interact with the CJR, given that such programs are necessary to ensure access and quality in all services but are particularly important and potentially burdensome when used to monitor both the entire episode of care as well as the post-episode period in which delayed care would appear. Commenters believe that CMS should implement those evaluation processes that are least disruptive to participants. Several commenters opined that any cases reimbursed under a ''shared accountability payment'' methodology such as CJR should not be subjected to claim denials as part of Medicare contractors' medical review activities. Other commenters requested that we explain the relative roles of RACs, QIOs, and other review contractors.

Other commenters believe that special controls and audits should be implemented to further protect beneficiaries. A commenter believes that CMS should require providers to submit annual reports that detail original care redesign objectives they agreed to implement, the progress they made in achieving those objectives and how achieving those objectives has been linked to gainsharing rewards. Another believed that we should institute a structured monitoring program to ensure compliance with the patient notice requirements, using a contractor such as a state survey agency, a QIO, or a hospital private accrediting body. Recommended elements of monitoring and control included the submission of any model notice in advance of its use,

certification of assurances of compliance by the hospital/physician auditing of compliance within the first 30 to 60 days of implementation of CJR and annual auditing of compliance thereafter.

CJR

*Response:* With respect to existing auditing programs, we agree that it is important to minimize the disruption of provider activity and to minimize the cost and burden of audits to the extent possible. We do not agree that services furnished to beneficiaries included in the CJR model should be excluded from MAC, RAC, ZPIC or other medical review or audit activity because CJR does not contain a substitute for these existing program integrity measures. Considerable financial risk is still retained by Medicare in that the direct payments to the hospital and PAC providers are still borne by Medicare. For example, if the participant hospital provided joint replacements on relatively healthy beneficiaries for whom the replacements were considered to be not medically necessary in accordance with a coverage decision or clinical guidelines, that overpayment could not be identified and corrected except through audit. Conversely, those lower cost procedures would reduce average cost and increase a participant hospital's reconciliation payment, benefitting the hospital while increasing costs borne by Medicare. Moreover, under the model the beneficiary remains responsible for the deductible for the hospital admission covered under Part A as well as copayments for many PAC services. We believe that ensuring that beneficiaries pay the correct deductibles and copayments is a function that is consistent with commenters' concerns for beneficiary protection as well as our obligation to enforce the statutory provisions that define Medicare benefits and beneficiary and provider obligations pursuant to those benefits.

We agree that contractors conducting audits or medical review to assess for delays in care or for other purposes may find and deny claims that were incorrectly billed. We also agree that there is a complex interaction between the denial of a service on a claim and its impact on the reconciliation process for the performance year under the CJR model, depending on the provider whose claim is denied, the timing of the adjustment relative to the model reconciliation, the limits of upside and downside risk, and other factors. For example, if a PAC claim is denied after final reconciliation, the hospital will still have incurred a cost approximately equal to the amount that was denied to the PAC provider because those costs would still be included in the calculation of the positive or negative NPRA as calculated in accordance with § 510.305. On the other hand, if the denial occurs prior to reconciliation, the hospital will have lower costs attributed to it as the cost of the service would be removed from the claims history. This will affect the NPRA as if the denied service had never been delivered and benefit the hospital by an amount that is approximately equal to the amount that was denied to the PAC provider. Given this complex interaction that can create diverse and opposing impacts but only in the setting of inappropriate (denied) claims, we do not believe that it is necessary or desirable to exclude services from medical review because they are delivered under the CJR model.

*G. Coordination With Other Agencies*

Impacts created by payment changes under this model are entirely internal to HHS operations; coordination with other agencies is not required outside of the usual coordination involved in the publication of all HHS regulatory changes.

## IV. Evaluation Approach

*A. Background*

The CJR model is intended to enable CMS to better understand the effects of bundled payments models on a broader range of Medicare providers than what is currently being tested under BPCI. Obtaining information that is representative of a wide and diverse group of hospitals will best inform us on how such a payment model might function were it to be more fully integrated within the Medicare program. All CMS models, which would include the CJR model, are rigorously evaluated on their ability to improve quality and reduce costs. In addition, we routinely monitor CMS models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. We outlined the proposed design and evaluation methods, data collection methods, key evaluation research questions, and the evaluation period and anticipated reports for the CJR model in the 2016 Comprehensive Care for Joint Replacement proposed rule (80 FR 4198).

*B. Design and Evaluation Methods*

Our evaluation approach for the CJR model will have elements in common with the standard Innovation Center evaluation approaches we have taken in other projects such as the BPCI initiative, ACE Demonstration, Pioneer ACO model, and other Innovation Center models. Specifically, the evaluation design and methodology for the CJR model would be designed to compare patterns of care among the CJR providers to patterns of care among non-CJR providers, potentially contrasted with historical differences in care between these two groups of providers.

Our evaluation methodology for this model builds upon the fact that MSAs were selected for participation in the model based on a stratified random assignment. In this approach, researchers evaluate the effects of the model on outcomes of interest by directly comparing MSAs that are randomly selected to participate in the model to a comparison group of MSAs that were not randomly selected for the model (but could have been). Randomized evaluation designs of this kind are widely considered the ''gold standard'' for social science and medical research because they ensure that the systematic differences are reduced between units that do and do not experience an intervention, which ensures that (on average) differences in outcomes between participating and non-participating units reflect the effect of the intervention.

The removal of the 8 MSAs that were previously selected but are now considered not eligible due the revision to the MSA exclusion rules does not compromise our proposed evaluation approach. The relative ranking of MSAs with respect to episode payments is unchanged by the new exclusions. The selected MSAs remain randomly selected and also remain distributed throughout the payment and population size dimensions. As with other evaluation issues, the methodological approach to examining and drawing conclusions about the impact of the model will be finalized in the Evaluation Contract.

We plan to use a range of analytic methods, including regression and other multivariate methods appropriate to the analysis of stratified randomized experiments to examine each of our measures of interest. Measures of interest could include, for example, quality of and access to care, utilization patterns, expenditures, and beneficiary experience. The evaluation would also include rigorous qualitative analyses in order to capture the evolving nature of the care model interventions.

In our design, we plan to take into account the impact of the CJR model at the geographic unit level, the hospital level, and the patient level. We are also considering various statistical methods

to address factors that could confound or bias our results. For example, we anticipate using statistical techniques to account for clustering of patients within hospitals and markets. Clustering allows our evaluation to compensate for commonalities in beneficiary outcomes by hospitals and by markets. Accounting for clustering ensures that we do not overstate our effective sample size by failing to account for the fact that performance of hospitals in a given market may not be fully independent of one another. Alternatively, accounting for clustering may improve statistical precision or allow us to better examine how patterns of performance vary across hospitals. For example, in cases where a large hospital consistently has poor performance, clustering would allow us to still be able to detect improved performance in the other, smaller hospitals in a market rather than place too much weight on the results of one hospital and potentially lead to mistaken inferences. Finally, we plan to use various statistical techniques to examine the effects of the CJR model while also taking into account the effects of other ongoing interventions such as BPCI, Pioneer ACOs, and Medicare Shared Savings Program. For example, we will consider additional regression techniques to help identify and evaluate the incremental effects of adding the CJR model in areas where patients and market areas are already subject to these other interventions as well as potential interactions among these efforts.

*C. Data Collection Methods*

We are considering multiple sources of data to evaluate the effects of the CJR model. We expect to base much of our analysis on secondary data sources such as Medicare FFS claims and required patient assessment instruments such as the Minimum Data Set (MDS) collected for SNF stays, the Patient Assessment Instrument for Inpatient Rehabilitation Facility (IRF–PAI) collected for IRF stays, and the Outcome and Assessment Information Set (OASIS) collected for home health episodes of care. The beneficiary claims data would provide information such as expenditures in total and by type of provider and service as well as whether or not there was an inpatient hospital readmission. The assessment tools would provide information on a beneficiary's functioning (for example, physical, psychological and psychosocial functioning).

In conjunction with the previously stated secondary data sources, we are considering a CMS-administered survey of beneficiaries who received an LEJR during the performance period. This survey would be administered to beneficiaries who either had received an LEJR under the CJR model or were selected as part of a control group. The primary focus of this survey would be to obtain information on the beneficiary's perception of their functional status before and after the LEJR as well as information on their pain and LE joint symptoms, and perceptions on access to care. The administration of this beneficiary survey would be coordinated with administration of the HCAHPS Survey so as to not conflict with or compromise the HCAHPS efforts. Likewise, we are considering a survey administered by CMS and guided interviews conducted by CMS with providers and suppliers including, but not limited to, orthopedic surgeons, initiating hospitals, and PAC providers participating furnishing services to beneficiaries included in the CJR model. These surveys would provide insight on beneficiaries' experience under the model and additional information on the care redesign strategies undertaken by health care providers.

In addition, we are considering CMS evaluation contractor-administered site visits with selected hospitals and PAC providers as well as focus groups with a range of populations such as PAC providers and orthopedic surgeons. We believe that these qualitative methods would provide contextual information that would help us better understand the dynamics and interactions occurring among CJR providers furnishing services included within a CJR episode. For example, these data could help us better understand hospitals' intervention plans as well as how they were implemented and what they achieved. Moreover, in contrast to relying on quantitative methods alone, qualitative approaches would enable us to view model nuances as well as identify factors that are associated with successful interventions and distinguish the effects of multiple interventions that may be occurring within participating providers, such as simultaneous ACO and bundled payment participation.

*D. Key Evaluation Research Questions*

Our evaluation would assess the impact of the CJR model on the aims of improved care quality and efficiency as well as reduced health care costs. This would include assessments of patient experience of care, utilization, outcomes, Medicare expenditures, provider costs, quality, and access. Our key evaluation questions would include, but are not limited to, the following:

- *Payment.* Is there a reduction in total Medicare expenditures in absolute terms or for subcategories of providers (for example, acute versus PAC providers, providers in certain geographic areas, providers within concentrated vs non-concentrated market areas or in urban vs rural areas)? Do the participants reduce or eliminate variations in utilization and expenditures or both that are not attributable to differences in health status? If so, how have they accomplished these changes?
- *Utilization.* Are there changes in Medicare utilization patterns overall or for specific types of providers or services? How do these patterns compare to historic patterns, regional variations, and national patterns of care? How are these patterns of changing utilization associated with Medicare payments, patient outcomes and general clinical judgment of appropriate care?
- *Outcomes/Quality.* Is there either a negative or positive impact on quality of care and patient experiences of care or both? Did the incidence of complications remain constant or decrease? Was there a change in beneficiaries' level of pain reduction, functional outcomes or return to independence under the model than relative to appropriate comparison groups? If so, how and for which beneficiaries?
- *Referral Patterns and Market Impact.* How, if at all, has the behavior in the selected geographic areas changed under the model? How have the referral patterns changed and for which type(s) of providers? Similarly, does the model have an impact on the number of patients with LEJR procedures and what types of patients are undergoing the procedure? To what extent, if any, is this related to gainsharing activities?
- *Unintended Consequences.* Did the CJR model result in any unintended consequences, including adverse selection of patients, access problems, cost shifting beyond the agreed upon episode, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, evidence of inappropriate referrals practices? If so, how, to what extent, and for which beneficiaries or providers?
- *Potential for Extrapolation of Results.* What was the typical patient case mix in the participating practices and how did this compare to regional and national patient populations? What were the characteristics of participating practices and to what extent were they representative of practices treating Medicare FFS beneficiaries? Was the model more successful in certain types

of markets? To what extent would the results be able to be extrapolated to similar markets and nationally or both?

• *Explanations for Variations in Impact.* What factors are associated with the patterns of results? Specifically, are the results related to the following?

++ Characteristics of the models including variations by year and factors such as presence of downside risk?

++ The participating hospital's specific features and ability to carry out their proposed intervention?

++ Characteristics and nature of interaction with partner providers and suppliers including orthopedic surgeons and PAC provider community?

++ Characteristics of the geographic area, such as market concentration or size of city and availability of PAC providers?

++ Characteristics associated with the patient populations served?

*E. Evaluation Period and Anticipated Reports*

As discussed in section III.C.2.a. of this final rule, each of the selected participants in the CJR model would have 5 performance years. The evaluation period would encompass all 5 performance years and up to 2 years after. We plan to evaluate the CJR model on an annual basis. However, we recognize that interim results are subject to issues such as sample size and random fluctuations in practice patterns. Hence, while we intend to have internal periodic summaries to offer useful insight during the course of the effort, a final analysis after the end of the 5 performance years will be important for ultimately synthesizing and validating results.

We sought comments on our design, evaluation, data collection methods, and research questions.

The following is a summary of the comments received and our responses.

*Comment:* A variety of commenters detailed evaluation topics in which they were particularly interested as follows:

• In the category of ''utilization,'' the following topics were highlighted as of interest to commenters: (1) An examination of utilization shifts between sites of care as well as an examination of the types of patients for which this occurs and if there was an impact on quality, health outcomes, and total spending; and (2) an examination of changes in types of devices being used in total joint replacement procedures compared to historical trends and other markets.

• In the category of ''outcomes and quality,'' the following topics were highlighted: an examination of the impact of the model on certain vulnerable subpopulations, including low-income individuals, individuals residing in low-access areas, and racial and ethnic minorities.

• In the category of ''market impact,'' the following topics were highlighted: an assessment of whether hospitals redesign or eliminate service lines; an assessment on the impact of the availability of services in a market; an assessment of the impact, if any, on the financial viability of PAC providers in impacted markets; the shifting of increased costs to other payers; and an exploration of the use of the gainsharing waiver, including the criteria hospitals use to identify preferred partner relationships and an examination of to whom gains are distributed.

• In the area of ''patient access,'' the following topics were mentioned: an examination of the extent to which beneficiary choice is preserved and whether or not hospitals steer patients towards certain providers; an assessment on the impact of the model on patient access to services including patient travel time; an assessment of the extent to which use of lower cost alternatives or lack of other enhancements to the patient experience led to changes in patient outcomes and satisfaction; and an evaluation of device offerings and patient access to various technologies for joint replacement.

• Within the category of exploring which factors are associated with ''variations'' in success, the following topics were mentioned: examining whether higher risk candidates for surgery are avoided or lower risk patients are inappropriately targeted for inclusion; an assessment of the impact of simultaneous incentives and participation in other models and programs that may impact the same patients or providers; an assessment of the variation in implementation by hospitals and the extent to which hospitals make a financial commitment to prepare staff and to undertake other activities to improve coordination; and an assessment of the use and impact of telehealth services and related efforts.

*Response:* The commenters' list of topics are in alignment with our stated areas of interest and will be considered in the development of the final evaluation plan in coordination with the contractor chosen to develop and carry out the model evaluation.

*Comment:* A variety of commenters, including MedPAC, presented measures and metrics that they believed would be important to include in the evaluation. In addition, a commenter suggested CMS make participation in a data registry a requirement for all participants in the model. Other suggested measures include the following:

• Readmission rates, complication rates, use of emergency room visits and observation stays, length of stay, changes in patient function, and patient experience in the assessment of the stinting of care.

• Number of days between discharge from the hospital to first PAC use, and number of days between hospital discharge and first physician visit to assess timely care coordination.

• Comparison of utilization rates for joint replacement procedures in markets included and excluded to monitor any increase.

• The development and implementation of true longitudinal outcome metrics.

*Response:* Commenters' measurement suggestions will be considered for inclusion in the development of the final evaluation plan. At this time, we do not plan to mandate participation in data registries for this model, given the significant implementation and administrative requirements this would require of providers.

*Comment:* A commenter suggested a particular methodological consideration relevant to the evaluation. Specifically, this commenter noted that the approach of excluding BPCI participating hospitals in an MSA has its own form of selection bias in that the new model will only include hospitals that have chosen not to participate in the BPCI initiative, and therefore is not necessarily a representative sample.

*Response:* We recognize the importance of this issue and agree that the model evaluation must account for any limitations on our ability to extrapolate the results achieved under this model. We will take this into consideration during the development of the final evaluation plan in coordination with the Evaluation Contractor.

*Comment:* While many commenters expressed support for a vigorous evaluation, commenters brought up specific concerns related to the anticipated burden associated with the evaluation. The commenters requested that CMS should implement an evaluation process that is least disruptive to participants (providers and beneficiaries) and incorporate lessons learned from BPCI participants into the development process. One area of concern was the patient survey. A commenter noted that for the BPCI evaluation, participants were requested to refrain from non-patient care-related survey efforts while the CMS BPCI survey was in the field. The commenter wrote that this hampered the bundlers'

ability to seek real-time feedback to improve care. Another commenter recommended minimizing as much as possible the use of site visits and noted a desire for CMS to consider compensating hospitals for the time associated with this effort. In addition, the commenter noted concern that CMS is requiring collaborators to participate in site visits.

*Response:* We acknowledge the concern related to the administrative burden associated with the evaluation and will endeavor to minimize it to the extent possible, while still ensuring a thorough assessment of the model and its impacts. With regard to the specific concerns, the survey of patients is considered to be a key component of the evaluation intended to address the issues of patient functional performance, pain reduction, and reductions in access. It is likely that we will continue the practice of asking for non-mandated and non-patient care-related surveys to be suspended for brief periods of time so as to not overburden patients. Hospitals' survey efforts are otherwise unaffected. We believe that the temporary disruption in provider efforts is worth gaining the detailed information on patient function, pain, and access that the surveys provide. With regards to site visits, we intend to use this data collection approach judiciously and will be mindful of the impact on providers.

Regarding collaborator agreements, we are requiring that participant hospitals include provisions that require all CJR collaborators to comply with any evaluation, monitoring, compliance, and enforcement activities performed by HHS or its designees for the purposes of operating the CJR model. We intend to be prudent in exercising this requirement but we believe that it is necessary to include, particularly related to the need to assess compliance with model requirements and patient quality of care. We do not anticipate that this will be a significant barrier to CJR collaborators signing agreements.

*Final Decision:* After consideration of the public comments received, we are finalizing the proposed approach to the evaluation without modification.

## V. Collection of Information Requirements

As stated in section1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

## VI. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of final rules.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

### *A. Statement of Need*

This final rule is necessary in order to implement and test a new payment and service delivery model under the authority of section 1115A of the Act, which allows the Innovation Center to test innovative payment and service delivery models in order to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. The underlying issue addressed by the CJR model is that under FFS, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of a treatment (an episode of care). Because the amount of payment is dependent on the volume of services delivered, this creates incentives for care that is fragmented, unnecessary or duplicative, while impeding the investment in quality improvement or care coordination that will maximize patient benefit. We anticipate the CJR model may reduce costs while maintaining or improving quality where the provision of ''bundled services'' in which all the services needed for a given episode of care are included in a single payment arrangement that provides incentives to promote high quality and efficient care.

This final rule will create and test the first bundled payment model under the Innovation Center authority in which providers will be required to participate, building on the experience of the current voluntary BPCI and previous ACE efforts. Testing the model in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize improvement in quality for common LEJR procedure episodes. This learning could inform future Medicare payment policy.

Under the CJR model, acute care hospitals in certain selected locations will receive retrospective bundled payments for episodes of care for LEJR or reattachment of a lower extremity. The proposed rule was developed based on the experiences we gained from the implementation of the Bundled Payments and Care Improvement Initiative and the ACE Demonstration to test bundled payments. We believe the model may benefit Medicare beneficiaries through improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivizing higher value care across the inpatient and PAC spectrum spanning the episode of care. It will also provide an opportunity to evaluate the nature and extent of reductions in the cost of treatment by providing financial incentives for providers to coordinate their efforts to provide services to meet patient needs and prevent future costs.

As detailed in Table 33, we estimate a total aggregate impact of $343 million in net Medicare savings over the duration of the model, CYs 2016 through 2020, from the implementation of the CJR model. This reflects the policies finalized in this rule, as well as updates to the data used for the impact analysis. We note that in the impact estimate in the proposed rule we had identified participant hospitals in the proposed selected 75 MSAs, though we inadvertently excluded some of those hospitals in our estimates presented in the proposed rule. For the impact analysis provided in this final rule, we revised our list of participant hospitals to include hospitals in the 67 MSAs selected for CJR and made the identification of hospitals consistent with how we identify hospitals in the selected MSAs in section III.A.3. of this final rule.

We note that we are posting the list of the participant hospitals in the selected MSAs on the CJR final rule Web site at *http://innovation.cms.gov/initiatives/CJR/* which generally reflects the hospitals used to estimate the impacts presented in this rule. Additionally, we note that this list will be updated throughout the model, to account for circumstances such as hospital mergers, BPCI termination, and new hospitals in the selected MSAs.

We note that we are finalizing the start date of this model to begin April 1, 2016 where the first performance year is 9 months and all other performance years begin January 1 and last 12 months. The estimates presented in this final rule reflect the changed start date

and the 9 month period for the first year of the model. These estimated impacts represent the estimated net effect of federal transfers under this model. Furthermore, the CJR model may benefit beneficiaries since the model requires participant hospitals to be accountable for 90-day episodes of care for Medicare beneficiaries with a LEJR, which may incentivize providers to improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

Our analysis of the model's effects shows that this final rule will trigger the threshold of ''an annual effect on the economy of $100 million or more'' under E.O. 12866. Accordingly it will also be a major rule under the Congressional Review Act, and we are required to prepare an analysis that presents the costs and benefits of this final rule. We have prepared an analysis that address benefits and costs that applies to ''economically significant'' or ''major'' rules. We solicited comment on the assumptions and analysis presented throughout this regulatory impact section.

The following is a summary of the comments received and our responses.

*Comment:* A commenter found our savings estimates to be overly optimistic where our assumptions were based on other models launched by CMMI. The commenter found that because those models were voluntary and participants would withdraw from those models at any time based on their performance under the model that we could not apply those assumptions for this model where we have selected participants and those participants are not able to withdraw from this model. As a result, the commenter found our savings estimates to be overly optimistic and aggressive. Another commenter found the savings estimate to be surprisingly small given the scope of the proposed model affecting providers in 75 MSAs. The commenter requested additional information regarding how much savings has been estimated for reduced complications and for reduced use of SNF, IRF, imaging studies, and other specific components.

*Response:* We acknowledge that many of our assumptions used for these estimates are based on our experience with other voluntary bundled payment models and demonstrations as that is the most recent information that we have regarding how we expect hospitals to perform under a bundled payment model. For this model, we have not assumed any changes in utilization, which is, in part, informed by on our experience in other bundled payment models. However, we expect significant variation among hospitals and among metropolitan areas, but we are unable to predict these. Additionally, we believe the CJR model has been designed to provide additional safeguards considering that we have selected the hospitals to participate in the model. Those safeguards for hospitals to be able to manage risk include a transition to regional pricing, delaying the start date from January 1, 2016 to April 1, 2016 and providing for more incremental stop-loss limits where hospitals are subject to a maximum 20 percent stop-loss limit for performance years 4 and 5. As described earlier, for this final rule, we are updating the data used for the impact analysis to participant hospitals in the now 67 MSAs for the final rule and we are including participant hospitals identified in the proposed rule but that had been inadvertently excluded from the estimates presented in the proposed rule. As a result, the estimates have changed for this final rule, not only to reflect the policy changes finalized in this rule, but also to reflect the additional hospitals included in the estimates. As previously noted, we are posting the list of the participant hospitals in the selected MSAs on the CJR model Web site at *http://innovation.cms.gov/initiatives/CJR/*.

*B. Overall Impact*

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. As previously stated, this final rule triggers these criteria.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, pre-empts state law, or otherwise has federalism implications. We do not believe that there is anything in this final rule that either explicitly or implicitly pre-empts any state law, and furthermore we do not believe that this final rule will have a substantial direct effect on state or local governments, preempt states law, or otherwise have a federalism implication.

*C. Anticipated Effects*

1. Overall Magnitude of the Model and Its Effects on the Market

According to Medicare FFS claims data in 2014, there were approximately 478,000 discharges for MS–DRGs 469 and 470 nationally. Based on the same data for 2014, we estimate that the participant hospitals had approximately 86,000 LEJR episodes (as defined in this model). The number of such procedures has grown in recent years, due both to the aging of the American population and to advances in medical technology and care that have made these operations less physically burdensome on patients and led to faster recovery times.

More uncertain are the total costs of these procedures. The mean estimated 90-day episode payment for LEJR procedures (defined as discharges for MS–DRG 469 and MS–DRG 470) is about $26,000 based on Medicare claims data for FY 2014 where approximately 55 percent of the spending is attributed to hospital inpatient services, 25 percent of spending is attributed to PAC services such as physical therapy (either ambulatory and in a facility) and 20 percent to physician, outpatient hospital and other spending.

We are testing the model in 67 MSAs out of the 196 MSAs initially deemed eligible for selection, as described previously in this final rule. We note that this is a change from the proposed rule where we had selected a proposed 75 MSAs but in this final rule, we are removing 8 MSAs from selection because they did not meet the updated eligibility criteria. Based on the selection methodology finalized in this rule, we estimate that the model will include about 23 percent of all LEJR episodes nationally. We estimate the model will apply to about $1.247 billion in episode spending in 2016 and $2.980 billion in episode spending in 2020 as displayed in Table 33 later in this section. As discussed subsequently in this analysis, this is likely to generate approximately a net amount of $343 million in savings to Medicare over the entire duration of the model. Annual reconciliation payments for each performance year may be greater than or less than the net change as detailed in Table 33 later in this section. In years 2019 and 2020 of the CJR model, we estimate a net change that is greater than the $100 million dollar threshold for economic significance.

There may also be spillover effects in the non-Medicare market, or even in the Medicare market in other areas as a result of this model. Recent research suggests that permanent changes in Medicare payment policy often have substantial effects on non-Medicare payers.[106] Because it is unclear whether and how this evidence applies to a test of a new payment model (as opposed to a change in permanent policy), our analyses assume that spillovers effects on non-Medicare payers will not occur, although this assumption is subject to considerable uncertainty. We welcomed comments on our assumptions and calculations.

2. Effects on the Medicare Program

The CJR model is a model involving an innovative mix of financial incentives for quality of care and efficiency gains within FFS Medicare for LEJR episodes. This model represents a new approach for the Medicare FFS program because it applies bundled payments to hospitals that might not otherwise participate in Innovation Center models or Medicare demonstrations and tests bundled payment models for episodes of care for LEJR procedures in multiple geographic areas. As such, we are interested in testing and evaluating the impact of a bundled payment approach for LEJR procedures in a variety of circumstances, especially among those providers that may not have decided to engage in programs or models in which Medicare makes payments differently than Medicare FFS.

As described earlier in this final rule in section III.B. of this final rule, episodes will begin with admission to an acute care hospital for an LEJR procedure that is paid under the IPPS through MS–DRG 469 or 470 and extend 90 days following discharge from the acute care hospital. The episode will include the LEJR procedure, inpatient stay, and all related care covered under Medicare Parts A and B within the 90 days after discharge, including hospital care, PAC, and physician services. Furthermore, we have designated participant hospitals as the episode initiators and to be financially responsible for episode cost under the CJR model. We will require all hospitals paid under the IPPS and physically located in selected geographic areas to participate in the CJR model, with limited exceptions. Eligible beneficiaries who receive care at these hospitals will automatically be included in the model. Geographic areas, based on MSAs, were selected for the model through a stratified random sampling methodology based on the following criteria: historical episode wage-adjusted payment quartiles and population size halves. We anticipate the CJR model may have financial and quality of care effects on non-hospital providers and suppliers that are involved in the care of Medicare beneficiaries with an LEJR episode, improving the coordination of items and services paid for through Medicare FFS, encouraging more provider investment in infrastructure and redesigned care processes for higher quality and more efficient service delivery, and incentivizing higher value care across the inpatient and PAC spectrum spanning the episode of care. However, the CJR model attributes episode spending and makes the retrospective reconciliation payment to or repayment from the participant hospital. Accordingly, our analysis examines the effects on participant hospitals, as they are the providers accountable for the episode payment under this model. Additionally, we will test the CJR model for a performance period beginning April 1, 2016 and ending December 31, 2020 and our estimates cover the duration of the model. We note that in this final rule, we are changing the start date of the model such that the first year of the model will begin April 1, 2016 and have a performance period of 9 months. All other performance years of the model will begin January 1 and have a performance period of 12 months.

As described earlier in this final rule, we will continue paying hospitals and other providers and suppliers according to the usual Medicare FFS payment systems during all performance years. After the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode, based on claims data, will be combined to calculate an actual episode payment. The actual episode payment is the sum of Medicare Part A and B claims payments for all related items and services furnished to a beneficiary during a CJR episode. The actual episode payment will then be reconciled against an established CJR target price, with consideration of additional payment adjustments based on quality performance and post episode spending. The amount of this calculation, if positive, will be paid to the participant hospital if the hospital has met the quality thresholds finalized in this rule. This payment is the reconciliation payment. If negative, the participant hospital will be required to make repayment to Medicare. We are phasing in the requirement that hospitals whose actual episode payments exceed their CJR target price to pay the difference back to Medicare beginning in performance year 2. Under this requirement, Medicare will not require repayment from hospitals for CJR episode spending above their target price in performance year 1. Lastly, we finalized to limit how much a hospital can gain or lose based on its reconciliation calculation with additional policies to further limit the risk of high payment cases for all participant hospitals and for special categories of hospitals.

Based on the mix of financial and quality incentives, the CJR model could result in a range of possible outcomes for participant hospitals. The effects on hospitals of potential savings and liabilities will have varying degrees.

Table 33 summarizes the estimated impact for the CJR model. Our model estimates that the Medicare program will save $343 million dollars over the 5 performance years (2016 through 2020). Savings to the Medicare program may be greater if providers are able to improve the coordination of care, invest in infrastructure, and redesign care processes to promote high quality and efficient service delivery. Costs to the Medicare program may increase if providers are able to use waivers provided under the model to increase

[106] See, for example, Jeffrey Clemens and Joshua D. Gottlieb. Forthcoming. ''In the Shadow of a Giant: Medicare'sMedicare's Influence on Private Physician Payments.'' *Journal of Political Economy.*

episode volume among beneficiaries that are expected to be less costly than the hospitals target price without the need for improving the coordination of care, or if there are declines in utilization independent of the model that are not incorporated in the prospective target prices. Our analysis to the best of our ability presents the cost and transfer payment effects of this final rule. We solicited comment on the assumptions and analysis presented.

a. Assumptions and Uncertainties

We used final action Medicare claims data from January 1, 2012 through March 31, 2015 as of October 2015 to simulate the impact that this model will have on Medicare spending for joint replacement episodes. This time period is consistent with the historical period that we are finalizing to use to calculate target prices for performance years 1 and 2 of the model as described in section III.C of this final rule (we note that for performance years 3 and 4, target prices will be calculated based on episodes that start between the period of January 1, 2014 to December 31, 2016. And for performance year 5, target prices will be calculated based on episodes that begin between the period of January 1, 2016 to December 31, 2018.) We applied the methodology provided in this final rule for calculating target prices for all hospitals that will be required to participate in the model, as discussed in section III.A. of this final rule, based on their performance from calendar years 2012 through 2014. Specifically, the estimates in this impact analysis reflect all IPPS hospitals in the selected MSAs and not participating in Model 1 or Phase II of BPCI Models 2 or 4 for the LEJR clinical episode as of October 2015. We identified the anchor hospitalizations based on claims with MS–DRG 469 and MS–DRG 470 and included the related spending that occurred 90 days after discharge. Also as finalized in this rule, we are risk stratifying for episodes with hip fractures for MS–DRG 469 and MS–DRG 470. For the purpose of the risk stratification, we identified anchor hospitalizations for MS–DRG 469 and MS–DRG 470 with hip fractures based on ICD–9–CM diagnosis codes reported on the anchor inpatient hospitalization claim. We removed payments excluded from the episode as not being associated with joint replacement care, as well as removing the IPPS add-on payments including disproportionate share hospital and indirect medical educational payments, new technology payments, uncompensated care payments, hospital value based purchasing payments, and hospital readmission reduction payments associated with the anchor hospitalization. We note that we have other payment exclusions in the calculation of the episode target price, in comparing actual episode payments with target prices, and in determining whether a reconciliation payment should be made to the hospital or repayment from the hospital should be made as described in section III.C. of this final rule. For the purpose of this impact analysis, we have only limited our calculations to remove the IPPS add-on payments reported on the IPPS claims including disproportionate share hospital and indirect medical educational payments, new technology payments, uncompensated care payments, hospital value based purchasing payments, and hospital readmissions reduction payments in calculating estimated target prices and in comparing the target price to actual episode payments. We then excluded episodes where the anchor hospitalization occurred in hospitals that are not paid under the IPPS. As finalized in this rule, we excluded episodes where the patient died during the 90 day episode. With the remaining episodes, we standardized episode payments to remove the variation in spending due to differences in the hospital's wage index. We trended utilization and prices in 2012 and 2013 to match 2014 national performance, and we incorporated the outlier policy to cap spending for high cost outlier episodes such that payments are capped at the MS–DRG anchor value that is two standard deviations above the mean as described in section III.C. of this final rule. After we pooled episodes for MS–DRGs 469 and 470 with and without hip fractures, we calculated average risk-stratified episode prices for each hospital and census region, as well as a hospital-specific weight representing a case mix value for each hospital that is dependent only on episode volume for MS–DRGs 469 and 470 with and without hip fractures, and the national anchor factor. We then calculated blended prices for each hospital, with prices set at two-thirds of the hospital's experience and one-third of the region's average experience for performance years 1 and 2 of the model, as one-third of the hospital's experience and two-thirds of the region's experience as used for performance year 3 of the model, and as the region's average experience for performance years 4 and 5 of the model. We made an exception for hospitals with low historical CJR episode volume defined in this final rule as those with fewer than 20 CJR episodes in total across the 3 historical years, by setting their target price as the region's experience. These average prices were then disaggregated based on the national anchor factor of average episode spending for MS–DRG 470 relative to MS–DRG 469, the computed hospital-specific weight, the hospital's wage index was then applied back to the price, and a Medicare discount was applied.

After calculating risk stratified target prices for MS–DRG 469 and 470 for each hospital appropriate for each performance year, we compared these target prices against actual performance in the 2014 calendar year. We capped actual spending for individual episodes based on the methodology in this final rule for high cost episodes. After incorporating the final policy for high cost episodes, total Medicare FFS spending in the 2014 calendar year for each hospital was reconciled against the target price and total number of episodes for the hospital. The aggregate impacts were then determined by multiplying by the total episodes for each MS–DRG.

As described earlier in this rule, we are finalizing our proposal to rebase the target prices in performance years 3 and 4 based on episodes that start between the period of January 1, 2014 to December 31, 2016 and rebase target prices for performance year 5 based on episodes that start between the period of January 1, 2016 to December 31, 2018.

The difference between each CJR episode's actual payment and the relevant target price (calculated as target price subtracted by CJR episode actual episode payment) will be aggregated for all episodes for a participant hospital within the performance year, creating the NPRA. As finalized in this rule, any positive NPRA amount greater than the stop-gain limit will be capped at the stop-gain limit of 5 percent for performance years 1 and 2 of the model, 10 percent in performance year 3 and 20 percent in performance years 4 and 5. We note this is a change from the proposed rule where we had proposed a stop-gain limit to be capped at 20 percent for each performance year of the model. In addition, any negative NPRA amount exceeding the stop-loss limit will be capped at the stop-loss limit as described in section III.C.8.b. of this final rule. To limit a hospital's overall repayment responsibility under this model, a 5 percent repayment limit in performance year 2, 10 percent repayment limit in performance year 3 and a 20 percent repayment limit in performance years 4 and 5. We note that this is a change from our proposed rule where we had proposed to set a 10

percent repayment limit in performance year 2 and 20 percent repayment limit in performance years 3 and subsequent years. For rural hospitals, MDHS, SCHs and RRCs, we are requiring a 3 percent repayment limit in performance year 2 and a 5 percent repayment limit in performance year 3 and subsequent years. Furthermore, as described earlier in this final rule, we are not finalizing our proposal that in order for a participant hospital to qualify for a reconciliation payment, a hospital must meet or exceed the 30th percentile benchmark for each of the following three quality measures in performance years 1 through 3 and 40th percentile in performance years 4–5:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550).
- Hospital-level 30-day, all-cause risk-standardized readmission rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1551).
- HCAHPS survey (NQF #0166).

Additionally, as described earlier in this final rule in section III.C.5., we are not finalizing our proposal that hospitals could qualify for a lower discount from 2 percent to 1.7 percent applied to their target episode price if they voluntarily submit patient-reported outcome measures data. Rather, we are finalizing the use of a composite quality score based on achievement and improvement on the THA/TKA Complications measure (NQF #1550) and the HCAHPS Survey measure (NQF #0116), as well as submission of THA/TKA voluntary PRO data, that will assign hospitals to be below acceptable, acceptable, good, and excellent. Hospitals assigned as 'below acceptable' would not be eligible for a reconciliation payment and would be subject to a 3 percent discount. Hospitals assigned as 'acceptable' would be eligible for a reconciliation payment and would be subject to a 3 percent discount. Hospitals assigned as 'good' would be eligible for a reconciliation payment and would be subject to a 2 percent discount. Lastly, hospitals assigned as 'excellent' would be eligible for a reconciliation payment and would be subject to a 1.5 percent discount. We note that in performance year 2 and 3, the discount for repayment would be 1 percentage point less than the discount applied for a reconciliation payment. We have used the following data to model the impact of this policy:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2015 based on the performance period of April 1, 2011 through March 31, 2014.
- HCAHPS survey (NQF #0166) reported on Hospital Compare in October 2015 based on the performance period of January 1, 2014 through December 31, 2014. To calculate improvement included in the composite quality score, we used the following data:
- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2014 based on the performance period of April 1, 2010 through March 31, 2013.
- HCAHPS survey (NQF #0166) reported on Hospital Compare in December 2014 based on the performance period of January 1, 2013 through December 31, 2013.

For the purpose of this analysis, we assumed that no hospitals voluntarily submitted patient reported outcome measures because we do not have the data to determine which hospitals in the model would submit this data. However, if we assumed that all hospitals in the model voluntarily submitted patient reported outcome measures, we would estimate that over the 5 performance years of the model, we would save $329 million (or 2.7% of total episode spend), as opposed to the projected estimates of $343 million (or 2.8% of total episode spend) in this final rule.. Hospitals located in selected MSAs were assigned to a performance percentile and assigned the corresponding quality performance score points listed in Table 16 of this final rule, based on their performance in the historical performance data described earlier. Hospitals that did not have a reported measure result were assigned to the 50th performance percentile. Hospitals assigned a quality measure performance percentile for the most recent year that improved by at least three deciles from the prior years' time period were quality improvement points. We used HCAHPS survey (NQF #0166) reported on Hospital Compare in October 2015 based on the performance period of January 1, 2014 through December 31, 2014 and Hospital-level (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2015 based on the performance period of April 1, 2011 through March 31, 2014 to model the hospital's performance in the most recent year. We used HCAHPS survey (NQF #0166) reported on Hospital Compare in December 2014 based on the performance period of January 1, 2013 through December 31,(RSCR)following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure results reported on Hospital Compare in July 2014 based on the performance period of April 1, 2010 through March 31, 2013 to calculate the hospital's performance in the prior year for the purpose of modeling a hospital's quality improvement. Composite quality scores, including quality improvement points on the two measures, were calculated for hospitals in selected MSAs, and hospitals were assigned to a quality category of ''below acceptable'', ''acceptable'', ''good'' or ''excellent'' based on their composite quality scores. As discussed in section III.C.5. of this final rule, composite quality scores will affect hospitals' eligibility for reconciliation payments and determine the amount of quality incentive payment a given hospital earns, which will affect hospitals' effective discount percentages at reconciliation.

In order to model payments in this impacts analysis, hospitals assigned as 'below acceptable' would not be eligible for a reconciliation payment and would be subject to a 3 percent effective discount percentage; hospitals assigned as 'acceptable' would be eligible for a reconciliation payment and would be subject to a 3 percent effective discount percentage; hospitals assigned as 'good' would be eligible for a reconciliation payment and would be subject to a 2 percent effective discount percentage, and hospitals assigned as 'excellent' would be eligible for a reconciliation payment and would be subject to a 1.5 percent effective discount percentage. We note that for performance years 2 and 3 of the model, for the purpose of repayment, the discount percentage is one percentage point lower than the effective discount percentage assigned for reconciliation payment. Due to limited data, for the purpose of modeling these estimates, we assumed that hospitals in the selected MSAs would have the same composite quality score throughout the 5 year performance period of the model.

To simulate the impact for performance year 1 or April 1 2016 through December 31, 2016, we calculated the NPRA assuming no downside risk to hospitals, and using the target price calculated for performance year 1, that is two-thirds hospital experience and one-third region experience. If the estimated NPRA is negative (that is, in the aggregate, the actual episode payments

for all episodes is greater than the target price multiplied by the number of episodes) for performance year 1, Medicare will not require repayment of the NPRA from the hospital because we have finalized no hospital responsibility for repayment for the first performance year. Additionally, as part of this estimate, we accounted for whether a hospital met the minimum composite quality score to be eligible for a reconciliation payment and to meet the quality incentive payment that adjusts the effective discount percentage to 2 percent or 1.5 percent. Lastly, we have applied the 5 percent stop-gain limit on the estimated reconciliation payments made to participant hospitals total reconciliation payments reflect what we will expect Medicare to pay hospitals due to normal claims variation, and due to a blended target price which rewards hospitals that already perform better than their regional average.

To simulate the impact in performance year 2, we calculated the NPRA with the 5 percent stop-loss and stop-gain limits applied, but only requiring repayments from hospitals for total spending that is above a 1 percent discount. Additionally, we accounted for whether hospitals would meet the quality payment incentives based on their performance for the THA/TKA complications rate and HCAHPs survey including eligibility for a reconciliation payment and the quality incentive discount at 2 percent or 1.5 percent. For the simulation in performance year 2, we used the target price calculated for performance year 2 that is two-thirds hospital experience and one-third regional experience. A 5 percent stop-loss limit was applied to repayments, and 3 percent stop-loss limit was applied for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers, and a 5 percent stop-gain limit was applied. We note that this is a change from the proposed rule where we proposed to apply a 10 percent stop-loss limit for all hospitals except for rural hospitals, sole community hospitals, Medicare dependent hospitals and rural referral centers.

To simulate the impact in performance year 3, we calculated the NPRA assuming 10 percent stop-gain and stop-loss limit and met the quality incentive scores for a reduced discount and for reconciliation payments, and requiring repayments from hospitals for total spending that is above the 2 percent discount. For the simulation in year 3, we used the target price calculated as one-third of the hospital's experience and two-thirds of the regional experience. We included a 10 percent stop-loss limit on repayments from acute care hospitals included in this analysis, but used a 5 percent stop-loss limit on reconciliation repayments from rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers. We note that this is a change from the proposed rule where we included a 20 percent stop-gain limit and 20 percent stop-loss limit on repayments for all hospitals with the exception of rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral centers

For performance years 4 and 5, the impact estimates were calculated in the same way except that the episode target prices are based on 100 percent of the regional experience and the stop-loss and stop-gain limits are set to 20 percent.

In the CJR model, we have finalized to include a total of 67 MSAs from 8 MSA groupings. IPPS hospitals located within the selected MSAs will be required to participate in this model unless they participate in BPCI as discussed earlier in this final rule in section III.A.

Additionally, we note for these estimates, we did not assume that participation in this model would result in in efficiency or utilization over the course of the model. Since the model provides hospitals with strong incentives to improve efficiency, however, it is plausible that improvement in efficiency (and corresponding reductions in utilization) could occur. If such improvements occurred, however, it would have a limited effect on the net savings generated by the model since the resulting reduction in episode savings would be offset approximately one-for-one by higher net reconciliation payments up to the stop-gain limits. Over the 5 performance years of the model, we estimate $343 million dollars in savings to the Medicare program, out of $12.299 billion in total episode spending.

TABLE 33—ESTIMATES OF RECONCILIATION PAYMENTS *

| | Performance year of the model | | | | | Across all 5 years of the model |
|---|---|---|---|---|---|---|
| | 2016 | 2017 | 2018 | 2019 | 2020 | |
| Total episode spending | $1,247 | $2,562 | $2,688 | $2,821 | $2,980 | $12,299 |
| Net reconciliation payments** | 11 | (36) | (71) | (120) | (127) | (343) |
| Reconciliation amounts | 11 | 23 | 30 | 52 | 55 | 170 |
| Repayment amounts | – | (58) | (101) | (172) | (182) | (513) |
| Net reconciliation as a percentage of total episode spend | 0.8% | −1.4% | −2.6% | −4.2% | −4.2% | −2.8% |

* Impact for 67 selected MSAs. All numbers rounded to closest million.
** Sum of reconciliation amount and repayment amount may not add to net reconciliation payment due to rounding.

These estimates contain a significant amount of uncertainty. As a result, this model could produce more significant Medicare savings or could result in additional costs to the Medicare program. The primary source of uncertainty stems from the normal variation in claim cost trends each year coupled with the cap on the repayment made at reconciliation. In addition, this analysis assumes no change in utilization both for the use of services within the bundled episode, as well as no change in total episodes among hospitals. The prospective prices for the CJR model incorporate price updates from the FFS payment systems, but assume no change in utilization for the performance years. If there is a national increase in utilization within each bundle that is independent of this model, then savings to the Medicare program may increase due to greater repayments paid back to Medicare. If there is a national decrease in utilization within each bundle that is independent of this model, then costs to the Medicare program may increase due to greater reconciliation payments paid by Medicare to hospitals. The results will also depend on the cumulative effects over time and across providers on whether and how the model changes either actual medical procedures or the allocations of payments among service providers. We will expect significant

variation among hospitals and among metropolitan areas, but are unable to predict these.

Additionally, although we project savings to Medicare under this model, as stated earlier, we note that under section 1115A(b)(3)(B) of the Act, the Secretary is required to terminate or modify a model unless certain findings can be made with respect to savings and quality after the model has begun. If during the course of testing the model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking as necessary.

b. Analyses

The first performance year of the model is expected to cost the Medicare program $11 million in reconciliation payments made by CMS to hospitals. No repayments from hospitals will be assessed because hospitals are not subject to downside risk in performance year 1. Hospitals that will receive reconciliation payments are the hospitals that provide lower cost care relative to their regional average. As stated earlier, we are finalizing that the first performance year will be 9 months beginning April 1, 2016 through December 31, 2016. The estimate reflects reconciliation payments made for a 9 month performance period.

In the second performance year of the model, participant hospitals on net are expected to pay $36 million to CMS. We are stipulating a 5 percent stop-loss and stop-gain limit for acute care hospitals, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which will be subject to a 3 percent stop-loss limit. These limits will cap the total amount of repayments paid by hospitals to CMS.

In the third performance year of the model, net reconciliation payments are expected to be $71 million in savings to the Medicare program. The additional savings in performance year 3 compared to performance year 2 can be attributed to the increase in the stop-loss and stop-gain limits to 10 percent for acute care hospitals, with exception for rural hospitals, sole community hospitals, Medicare dependent hospitals, and rural referral center hospitals which will be subject to a 5 percent stop-loss limit.

For performance years 4 and 5 of the model, the episode target price will be based on full regional pricing. This creates great variation between the target price and hospitals own experience. Therefore, the stop-gain and stop-loss limits of 20 percent on reconciliation payments are estimated to have a larger impact. As a result, net payments are expected to be $120 million dollars from hospitals to the Medicare program in the fourth year and $127 million in the fifth year. These estimated savings in years 4 and 5 represent 4.2 percent of total episode spending in those years.

The total savings to the Medicare program after 5 years of the model are expected to be $343 million dollars out of $12.299 billion dollars or 2.8 percent in total episode spending. Due to the uncertainty of estimating this model, actual results could be significantly higher or lower than this estimate.

c. Further Consideration

We can use our experience in previous implementation of bundled payment models to help inform our impact analyses. We have previously used our statutory authority to create payment models such as the BPCI initiative and the ACE Demonstration to test bundled payments. Under the authority of section 1866C of the Act, CMS funded a 3-year demonstration, the ACE Demonstration. The demonstration used a prospective global payment for a single episode of care as an alternative approach to payment for service delivery under traditional Medicare FFS. The episode of care was defined as a combination of Parts A and B services furnished to Medicare FFS beneficiaries during an inpatient hospital stay for any one of a specified set of cardiac and orthopedic MS DRGs. The MS DRGs tested included 469 and 470, which are included in the CJR model. The discounted bundled payments generated an average gross savings to Medicare of $585 per episode for a total of $7.3 million across all episodes (12,501 episodes) or 3.1 percent of the total expected costs for these episodes. After netting out the savings produced by the Medicare Parts A and B discounted payments and some increased PAC costs that were observed at two sites, Medicare saved approximately $4 million, or 1.72 percent of the total expected Medicare spending.

Additionally, we are currently testing the BPCI initiative. Under the initiative, entities enter into payment arrangements with CMS that include financial and performance accountability for episodes of care. Episodes of care under the BPCI initiative begin with either an—(1) Inpatient hospital stay; or (2) PAC services following a qualifying inpatient hospital stay and include tests of LEJR episodes. The BPCI initiative is evaluating the effects of episode based payment approaches on patient experience of care, outcomes, and cost of care for Medicare FFS beneficiaries. Although there is some evidence from BPCI and ACE suggesting that providers may improve their performance, both of these initiatives were voluntary, and the participants that volunteered to participate may be in a better position to reduce episode spending relative to the average provider. We believe that our experiences with BPCI support the design of the CJR Model.

3. Effects on Beneficiaries

In 2014, approximately 430,000 Medicare beneficiaries had discharges for LEJRs (MS–DRG 469 and MS–DRG 470) nationally. We anticipate that the CJR model may benefit beneficiaries receiving LEJRs because the intent of the model is to test whether providers under this bundled payment system are able to improve the coordination and transition of care, invest in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivize higher value care across the inpatient and PAC spectrum spanning the episode of care.

We have finalized several quality of care and patient experience measures to evaluate participant hospitals in the CJR model with the intent that it will encourage the provider community to focus on and deliver improved quality care for the Medicare beneficiary. We are finalizing to adopt and publicly report two hospital level quality of care measures for the CJR model. Those measures include a complication measure and a patient experience survey measure. In addition, we are finalizing to voluntarily collect data to develop a hospital-level measure of patient reported outcomes following an elective primary total hip or total knee arthroplasty to be used in future years of the model. We finalized to use these measures to assess the success of the model and to monitor for beneficiary safety. The accountability of participant hospitals for both quality and cost of care provided for Medicare beneficiaries with an LEJR episode provides the hospitals with new incentives to improve the health and well-being of the Medicare beneficiaries they treat.

Additionally, the model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program. Under the CJR model, eligible beneficiaries who choose to receive services from a participant hospital will not have the option to opt out of inclusion in the model. Although the CJR model allows hospitals to enter into risk-sharing arrangements with certain other providers and these hospitals may recommended those providers to the

beneficiary, hospitals may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality and we will use our existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. As described earlier in this final rule, given that participant hospitals will receive a reconciliation payment when they are able to reduce average costs per case and meet quality thresholds, they could have an incentive to avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. We intend to monitor the claims data from participant hospitals—for example, to compare a hospital's case mix relative to a pre-model historical baseline to determine whether complex patients are being systematically excluded. Furthermore, we also will require providers to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice.

We are implementing several safeguards to ensure that Medicare beneficiaries do not experience a delay in services. We believe that the longer the episode duration, the lower the risk of delaying care beyond the episode duration, and we believe that a 90 day episode is sufficiently long to minimize the risk that any LEJR related care will be delayed beyond the end of the episode. Moreover, we have finalized as part of the payment definition (see section III.C. of this final rule) that certain post-episode payments occurring in the 30 day window subsequent to the end of the 90-day episode will be counted as an adjustment against savings. Importantly, approaches to saving costs will include taking steps that facilitate patient recovery, that shorten recovery duration, and that minimize post-operative problems that might lead to readmissions. Thus, the model itself rewards better patient care.

Lastly, we note that Medicare payments for services will continue to be made for each Medicare FFS payment system under this model, and will include normal beneficiary copayments, deductibles, and coinsurance. We expect and assume that beneficiary payments will not be affected, as only the hospital will be subject to the reconciliation process. Beneficiaries may benefit if providers are able to systematically improve the quality of care while reducing costs. We welcomed public comments on our estimates of the impact of our proposals on Medicare beneficiaries. We did not receive any comments on our estimates of the impact of our policies on Medicare beneficiaries.

4. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.5 to $38.5 million in any 1 year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at *http://www.sba.gov/content/small-business-size-standards*.

For purposes of the RFA, we generally consider all hospitals and other providers and suppliers to be small entities. We believe that the provisions of this final rule relating to acute care hospitals will have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, SNFs, physical therapists, and other providers.

Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this final rule discusses aspects of the model that may or will affect them, we have no reason to assume that these effects will reach the threshold level of 5 percent of revenues used by HHS to identify what are likely to be ''significant'' impacts. Although LEJR procedures (MS–DRGs 469 and 470) are among the most common surgical procedures undergone by Medicare beneficiaries, they are only about 5 percent of all acute hospital discharges.[107] We assume that all or almost all of these entities will continue to serve these patients, and to receive payments commensurate with their cost of care. Such changes occur frequently already (for example, as both hospital affiliations and preferred provider networks change), and we have no reason to assume that this will change significantly under the model.

Accordingly, we have determined that this final rule will not have a significant impact on a substantial number of small entities. We solicited public comments on our estimates and analysis of the impact of our proposals on those small entities.

*Comment:* We received a comment regarding our determination that this rule would not have a significant impact on a substantial number of small entities. The commenter stated that because LEJRs are among the most common surgical procedures for Medicare beneficiaries, a significant number of Medicare patients are receiving their rehabilitation treatment outside the hospital at independent physical therapy practices. Thus, the commenter stated that the analysis erroneously focused on hospitals and neglected to address the impact that this model would have on small independent physical therapy practices.

*Response:* We acknowledge that many providers, besides hospitals, are involved in the continuum of care for Medicare beneficiaries in the 90-day post discharge LEJR episodes and will be impacted by this model. However, we have focused this impact analysis on the providers that are directly financially responsible for the episode of care for LEJRs, the IPPS hospitals in the selected MSAs. Many of the policies finalized in this rule are directed towards the IPPS hospitals because they are financially at risk under this model. Accordingly, the estimates in this impact analysis are for the hospitals participating in this model and we are unable to estimate the impacts on non-hospital providers and suppliers that are involved in the care for beneficiaries with LEJR episodes.

5. Effects on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a proposed rule or final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, a small rural hospital is defined as a hospital that is located outside of an MSA and has fewer than 100 beds. We note that, according to this definition, the CJR model will not include any rural hospitals given that the CJR model will only include hospitals located in MSAs, as discussed in section III.A of this final rule. However, we also note that as discussed in section III.C.8. of this final rule, for purposes of our policy finalized in this rule to include a more protective stop-loss policy for certain hospitals, we are finalizing to define a rural hospital as an IPPS hospital that is either located

[107] Medicare Inpatient Claims data from January-December 2014, Chronic Conditions Warehouse.

in a rural area in accordance with § 412.64(b) or in a rural census tract within an MSA defined at § 412.103(a)(1) or has reclassified to rural in accordance with § 412.103. Thus, the CJR model will affect some rural hospitals, as discussed previously in section III.C.8. of this final rule.

Because of our concerns that rural hospitals may have lower risk tolerance and less infrastructure and support to achieve efficiencies for high payment episodes, we are implementing additional financial protections for certain categories of hospitals, including rural hospitals. In performance year 2, a hospital could owe Medicare no more than 5 percent of the target price multiplied by the number of the hospital's LEJR episodes in CJR as we phase in repayment responsibility under the model and in performance year 3, a hospital could owe Medicare no more than 10 percent. In performance year 4 and 5 when full repayment responsibility is in place, no more than 20 percent of the target price multiplied by the number of the hospital's LEJR episodes in CJR could be owed by a hospital to Medicare. However, for rural hospitals, Medicare Dependent Hospitals, RRCs and Sole Community Hospitals, we are implementing a lower stop loss limit policy of 3 percent of episode payments for these categories of hospitals. More specifically, in performance year 2, a rural hospital, MDH, RRC, or SCH could owe Medicare no more than 3 percent of the target price multiplied by the number of the hospital's episodes in CJR. In performance years 3 through 5, such a hospital could owe Medicare no more than 5 percent of the target price multiplied by the number of the hospital's episodes. We are finalizing these additional protections, and we estimate that approximately 9 percent of participant hospitals are rural hospitals, MDHs, RRCs and SCHs that will be subject to these protections.

Because LEJR procedures (MS–DRGs 469 and 470) account for only about 5 percent of all discharges, because relatively few of these procedures are performed at small rural hospitals, and because our model is designed to minimize adverse effects on rural hospitals, we do not believe that rural hospitals will experience significant adverse economic impacts. Accordingly, we conclude that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

We solicited public comments on our estimates and analysis of the impact of our proposals on those small rural hospitals.

*Comment:* A commenter questioned our determination that this rule will not have a significant impact on small rural hospitals. The commenter was concerned that the proposed rule could cause significant harm to rural hospitals, particularly rural hospitals paid under cost reimbursement like CAHs. The commenter believed that because swing beds offered in CAHs are reimbursed at a higher cost based rate than SNFs, hospitals would divert their patients from the CAH to a SNF. This would result in a significant financial impact on the CAHs who would lose their swing bed patients.

*Response:* We appreciate the comment regarding the impact of this model on rural providers, particularly CAHs. CAHs have been excluded as episode initiators in this model as IPPS hospitals are the selected participants that are financially responsible for the 90-day LEJR episode. However, we anticipate that rural providers such as CAHs, RHCs and FQHCs would be involved in the care provided to Medicare beneficiaries with a 90-day LEJR episode. It is possible that as participant hospitals implement changes to improve efficiencies in episode spending that they may change their care coordination patterns with consideration to costs and quality, and it would affect other provider types involved in the care continuum for LEJR patients. As described earlier in this final rule, we recognize that rural IPPS hospitals, SCHs, MDH and RRCs often serve as the only access of care for beneficiaries living in rural areas and may have fewer resources to contain costs under this model and may have more limited options on providers to coordinate care with, such as CAHs that are reimbursed at a higher cost based rate. As a result, we have provided for more protective stop-loss limits for these groups of IPPS hospitals in order to be able to include them in the model while alleviating some financial risk and we believe that this model will not have a significant impact on the operations of a substantial number of small rural hospitals. Because IPPS hospitals are financially at risk in this model, the estimates in this impact analysis are for the hospitals selected to be in this model and we are unable to estimate the impacts on non-hospital rural providers that are involved in the care for beneficiaries with LEJR episodes.

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately $144 million. This final rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of $144 million in any 1 year.

*D. Alternatives*

Throughout this final rule, we have identified our policies and alternatives that we have considered, and provided information as to the effects of these alternatives and the rationale for each of the policies. In the proposed rule we solicited and welcomed comments on our proposals, on the alternatives we identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these. We note that our estimates are limited to the IPPS hospitals that are selected to participate in this model. This final rule will not directly affect hospitals that are not participating in the model. However, it may encourage innovations in health care delivery in other areas or in care reimbursed through other payers. For example, a hospital and affiliated providers may choose to extend their arrangements to all joint replacement procedures they provide, not just those reimbursed by Medicare. Alternatively, a hospital and affiliated providers in one city may decide to hold themselves forth as ''centers of excellence'' for patients from other cities, both those included and not included in the model. In the proposed rule we welcomed comments that address these or other possibilities. We did not receive any comments on the alternatives considered.

*E. Accounting Statement*

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*) in Table 34, we have prepared an accounting statement showing the classification of transfers, benefits, and costs associated with the provisions in this final rule. The accounting statement is based on estimates provided in this regulatory impact analysis. As described in Table 33, we estimate this final model will result in savings to the federal government of $343 million over the 5 performance years of the model from 2016 to 2020. The following Table 34 shows the annualized change in (A) net federal monetary transfers, and (B) potential reconciliation payments to participating hospitals net of repayments from participant hospitals

that is associated with the provisions of this final rule as compared to baseline. In Table 34, the annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $63 million and $65 million respectively.

TABLE 34—ACCOUNTING STATEMENT ESTIMATED IMPACTS

| Category | Primary estimate | Source citation (RIA, preamble, etc.) |
|---|---|---|
| **BENEFITS** | | |
| Annualized monetized transfers: Discount rate: 7% | $63 million | Change from baseline to final changes (Table 18). |
| Annualized monetized transfers: Discount rate: 3% | 65 million.. | |
| From whom to whom? | From Participant IPPS Hospitals to Federal Government. | |

*F. Conclusion*

The preceding analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule with a significant economic effect. As a result of this final rule, we estimate of the financial impact of the CJR model for CYs 2016 through 2020 will be net federal savings of $343 million over a 5 year period. The annualized change in payments based on a 7 percent and 3 percent discount rate, results in net federal monetary transfer from the participant IPPS hospitals to the federal government of $63 million and $65 million respectively.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

**List of Subjects for 42 CFR Part 510**

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at section 1115A of the Social Security Act, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

**SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS**

■ 1. Revise the heading of subchapter H to read as set forth above.

■ 2. Part 510 is added to subchapter H to read as follows:

## PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

Sec.



**Authority:** Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

### Subpart A—General Provisions

#### § 510.1 Basis and scope.

(a) *Basis.* This part implements the test of the Comprehensive Care for Joint Replacement model under section 1115A of the Act. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) The participants in the Comprehensive Care for Joint Replacement model.

(2) The episodes being tested in the model.

(3) The methodology for pricing and payment under the model.

(4) Quality performance standards and quality reporting requirements.

(5) Safeguards to ensure preservation of beneficiary choice and beneficiary notification.

#### § 510.2 Definitions.

For the purposes of this part, the following definitions are applicable unless otherwise stated:

*ACO* stands for accountable care organization.

*Actual episode payment* means the sum of Medicare claims payments for items and services that are included in the episode in accordance with § 510.200(b), excluding the items and services described in § 510.200(d).

*Alignment payment* means a payment from a CJR collaborator to a participant hospital under a sharing arrangement, for only the purpose of sharing the

participant hospital's responsibility for repayments to Medicare.

*Anchor hospitalization* means the initial hospital stay upon admission for a lower extremity joint replacement.

*BPCI* stands for the Bundled Payment for Care Improvement initiative.

*CEC* stands for Comprehensive ESRD Care Initiative.

*CCN* stands for CMS certification number.

*CJR collaborator* means one of the following Medicare-enrolled persons or entities that enters into a sharing arrangement:

(1) Skilled nursing facility (SNF).

(2) Home health agency (HHA).

(3) Long-term care hospital (LTCH).

(4) Inpatient rehabilitation facility (IRF).

(5) Physician.

(6) Nonphysician practitioner.

(7) Provider or supplier of outpatient therapy services.

(8) Physician group practice (PGP).

*CJR reconciliation report* means the report prepared after each reconciliation that CMS provides to each participant hospital notifying the participant hospital of the outcome of the reconciliation.

*Collaborator agreement* means a written, signed agreement between a CJR collaborator and a participant hospital that meets the requirements of § 510.500(c).

*Composite quality score* means a score computed for each participant hospital to summarize the hospital's level of quality performance and improvement on specified quality measures as described in § 510.315.

*Core-based statistical area (CBSA)* means a statistical geographic entity consisting of the county or counties associated with at least one core (urbanized area or urban cluster) of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core.

*Critical access hospital (CAH)* means a hospital designated under subpart F of part 485 of this chapter.

*Distribution arrangement* means a financial arrangement between a PGP that is a CJR collaborator and a practice collaboration agent in which the PGP distributes some or all of a gainsharing payment that it received from a participant hospital.

*Distribution payment* means a payment made by a PGP that is a CJR collaborator to a practice collaboration agent under a distribution arrangement.

*DME* stands for durable medical equipment.

*EFT* stands for electronic funds transfer.

*Episode of care (or Episode)* means all Medicare Part A and B items and services described in § 510.200(b) (and excluding the items and services described in § 510.200(d)) that are furnished to a beneficiary described in § 510.205 during the time period that begins with the beneficiary's admission to an anchor hospitalization and ends on the 90th day after the date of discharge from the anchor hospitalization, with the day of discharge itself being counted as the first day of the 90-day post-discharge period.

*Episode target price* means the amount determined in accordance with § 510.300 and applied to an episode in determining a net payment reconciliation amount.

*ESRD* stands for end stage renal disease.

*Gainsharing payment* means a payment from a participant hospital to a CJR collaborator, under a sharing arrangement, composed of only reconciliation payments or internal cost savings or both.

*HHA* stands for home health agency.

*HCAHPS* stands for Hospital Consumer Assessment of Healthcare Providers and Systems.

*HCPCS* stands for CMS Common Procedure Coding System.

*Historical episode payment* means the most recent 3 years of expenditures for an episode in a given participant hospital.

*ICD–CM* stands for International Classification of Diseases, Clinical Modification.

*Inpatient prospective payment systems (IPPS)* means the payment systems for subsection (d) hospitals as defined in section 1886(d)(1)(B) of the Act.

*Internal cost savings* means the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CJR episodes of care. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

*IPF* stands for inpatient psychiatric facility.

*IPPS hospital (or hospital)* means a provider subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

*IRF* stands for inpatient rehabilitation facility.

*Lower-extremity joint replacement (LEJR)* means any procedure that is within MS–DRG 469 or 470, including lower-extremity joint replacement procedures or reattachment of a lower extremity.

LTCH stands for long-term care hospital.

*Medicare severity diagnosis-related group (MS–DRG)* means, for the purposes of this model, the classification of inpatient hospital discharges updated in accordance with § 412.10 of this chapter.

*Medicare-dependent, small rural hospital (MDH)* means a specific type of hospital that meets the classification criteria specified under § 412.108 of this chapter.

*Member of the PGP* or *PGP member* means a physician, nonphysician practitioner, or therapist who is an owner or employee of the PGP and who has reassigned to the PGP his or her right to receive Medicare payment.

*Metropolitan Statistical Area (MSA)* means a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000.

*Net payment reconciliation amount (NPRA)* means the amount determined in accordance with § 510.305(e).

*Nonphysician practitioner* means (except for purposes of subpart G of this part) one of the following:

(1) A physician assistant who satisfies the qualifications set forth at § 410.74(a)(2)(i) and (ii) of this chapter.

(2) A nurse practitioner who satisfies the qualifications set forth at § 410.75(b) of this chapter.

(3) A clinical nurse specialist who satisfies the qualifications set forth at § 410.76(b) of this chapter.

(4) A certified registered nurse anesthetist (as defined at § 410.69(b)).

(5) A clinical social worker (as defined at § 410.73(a)).

(6) A registered dietician or nutrition professional (as defined at § 410.134).

*NPI* stands for National Provider Identifier.

*OIG* stands for the Department of Health and Human Services Office of the Inspector General.

*PAC* stands for post-acute care.

*Participant hospital* means an IPPS hospital (other than those hospitals specifically excepted under § 510.100(b)) with a CCN primary address in one of the geographic areas selected for participation in the CJR model in accordance with § 510.105, as of the date of selection or any time thereafter during any performance period.

*PBPM* stands for per-beneficiary-per-month.

*Performance year* means one of the years in which the CJR model is being tested. Performance years for the model correlate to calendar years with the

exception of performance year 1, which is April 1, 2016 through December 31, 2016.

*PGP* stands for physician group practice.

*Physician* has the meaning set forth in section 1861(r) of the Act.

*Post-episode spending amount* means the sum of Medicare Parts A and B payments for items and services that are furnished to a beneficiary within 30 days after the end of the beneficiary's episode.

*Practice collaboration agent* means a PGP member who has entered into a distribution arrangement with the same PGP of which he or she is a member and who has not entered into a collaborator agreement with a participant hospital.

*Provider of outpatient therapy services* means a provider or supplier furnishing one or more of the following:

(1) Outpatient physical therapy services as defined in § 410.60 of this chapter.

(2) Outpatient occupational therapy services as defined in § 410.59 of this chapter.

(3) Outpatient speech-language pathology services as defined in § 410.62 of this chapter.

*Quality improvement points* are points that CMS adds to a participant hospital's composite quality score for a measure if the hospital's performance percentile on an individual quality measure increases from the previous performance year by at least 3 deciles on the performance percentile scale.

*Quality performance points* are points that CMS adds to a participant hospital's composite quality score for a measure based on the performance percentile scale and for successful data submission of patient-reported outcomes.

*Reconciliation payment* means a payment made by CMS to a CJR participant hospital as determined in accordance with § 510.305(f).

*Region* means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau.

*Repayment amount* means the amount owed by a participant hospital to CMS, as reflected on a reconciliation report.

*Rural hospital* means an IPPS hospital that meets one of the following definitions:

(1) Is located in a rural area as defined under § 412.64 of this chapter.

(2) Is located in a rural census tract defined under § 412.103(a)(1) of this chapter.

(3) Has reclassified as a rural hospital under § 412.103 of this chapter.

*Rural referral center (RRC)* has the same meaning given this term under § 412.96 of this chapter.

*Sharing arrangement* means a financial arrangement between a participant hospital and a CJR collaborator for the sole purpose of making gainsharing payments or alignment payments under the CJR model.

*Sole community hospital (SCH)* means a hospital that meets the classification criteria specified in § 412.92 of this chapter.

*SNF* stands for skilled nursing facility.

*Therapist* means one of the following as defined at § 484.4:

(1) Physical therapist.

(2) Occupational therapist.

(3) Speech-language pathologist.

*TKA/THA* stands for total knee arthroplasty/total hip arthroplasty.

*TIN* stands for taxpayer identification number.

## Subpart B—Comprehensive Care for Joint Replacement Program Participants

### § 510.100 Episodes being tested.

(a) *Initiation of an episode.* An episode is initiated when a participant hospital admits a Medicare beneficiary described in § 510.205 for an anchor hospitalization.

(b) *Exclusions.* A hospital is excluded from being a participant hospital, but only so long as any of the following conditions apply:

(1) The hospital is an episode initiator for an LEJR episode in the risk-bearing period of Models 2 or 4 of BPCI.

(2) The hospital is participating in Model 1 of BPCI.

(3) These exclusions cease to apply as of the date that the hospital no longer meets any of the conditions specified in this paragraph.

### § 510.105 Geographic areas.

(a) *General.* The geographic areas for inclusion in the CJR model are obtained based on a stratified random sampling of certain MSAs in the United States. All counties within each of the selected MSAs are selected for inclusion in the CJR model.

(b) *Stratification criteria.* Geographic areas in the United States are stratified according to the characteristics that CMS determines are necessary to ensure that the model is tested on a broad range of different types of hospitals that may face different obstacles and incentives for improving quality and controlling costs.

(c) *Exclusions.* CMS excludes from the selection of geographic areas MSAs that met the following criteria:

(1) Had fewer than 400 episodes between July 1, 2013 and June 30, 2014.

(2) Had fewer than 400 non-Model 1, 2, or 4 BPCI episodes as of October 1, 2015.

(3) Failed either or both of the following rules regarding participation in BPCI:

(i) More than 50 percent of eligible episodes initiated in a BPCI Model 2 or 4 initiating hospital.

(ii) More than 50 percent of eligible episodes that included SNF or HHA services, where the SNF or HHA services were furnished by a BPCI Model 3 initiating HHA or SNF.

(4) For MSAs including both Maryland and non-Maryland counties, more than 50 percent of eligible episodes were initiated at a Maryland hospital.

## Subpart C—Scope of Episodes

### § 510.200 Time periods, included and excluded services, and attribution.

(a) *Time periods.* All episodes must begin on or after April 1, 2016 and end on or before December 31, 2020.

(b) *Included services.* All Medicare Parts A and B items and services are included in the episode, except as specified in paragraph (d) of this section. These services include, but are not limited to, the following:

(1) Physicians' services.

(2) Inpatient hospital services (including hospital readmissions).

(3) IPF services.

(4) LTCH services.

(5) IRF services.

(6) SNF services.

(7) HHA services.

(8) Hospital outpatient services.

(9) Outpatient therapy services.

(10) Clinical laboratory services.

(11) DME.

(12) Part B drugs and biologicals.

(13) Hospice services.

(14) PBPM payments under models tested under section 1115A of the Act.

(c) *Episode attribution.* All items and services included in the episode are attributed to the participant hospital at which the anchor hospitalization occurs.

(d) *Excluded services.* The following items, services, and payments are excluded from the episode:

(1) Hemophilia clotting factors provided in accordance with § 412.115 of this chapter.

(2) New technology add-on payments, as defined in part 412, subpart F of this chapter.

(3) Transitional pass-through payments for medical devices as defined in § 419.66 of this chapter.

(4) Items and services unrelated to the anchor hospitalization, as determined by CMS. Excluded services include, but are not limited to, the following:

(i) Inpatient hospital admissions for MS–DRGs that group to the following categories of diagnoses:

(A) Oncology.

(B) Trauma medical.

(C) Chronic disease surgical, such as prostatectomy.

(D) Acute disease surgical, such as appendectomy.

(ii) Medicare Part B services, as identified by the principal ICD–CM diagnosis code on the claim (based on the ICD–CM version in use during the performance year) that group to the following categories of diagnoses:

(A) Acute disease diagnoses, such as severe head injury.

(B) Certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis basis depending on whether the condition was likely to have been affected by the LEJR procedure and recovery period or whether substantial services were likely to be provided for the chronic condition during the episode. Such chronic disease diagnoses are posted on the CMS Web site and may be revised in accordance with paragraph (e) of this section.

(iii) Certain PBPM payments under models tested under section 1115A of the Act. PBPM model payments that CMS determines to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in this paragraph.

(A) The list of excluded PBPM payments is posted on the CMS Web site and are revised in accordance with paragraph (e) of this section.

(B) Notwithstanding the foregoing, all PBPM model payments funded from CMS' Innovation Center appropriation are excluded from the episode.

(5) Certain incentive programs and add on payments under existing Medicare payment systems in accordance with § 510.300(b)(6) of this chapter.

(6) Payments for otherwise included items and services in excess of 2 standard deviations above the mean regional episode payment in accordance with § 510.300(b)(5) of this chapter.

(e) *Updating the lists of excluded services.* (1) The list of excluded MS–DRGs, ICD–CM diagnosis codes, and CMS model PBPM payments are posted on the CMS Web site.

(2) On an annual basis, or more frequently as needed, CMS updates the list of excluded services to reflect annual coding changes or other issues brought to CMS's attention.

(3) CMS applies the following standards when revising the list of excluded services for reasons other than to reflect annual coding changes:

(i) Items or services that are directly related to the LEJR procedure or the quality or safety of LEJR care would be included in the episode.

(ii) Items or services for chronic conditions that may be affected by the LEJR procedure or post-surgical care would be related and included in the episode.

(iii) Items and services for chronic conditions that are generally not affected by the LEJR procedure or post-surgical care would be excluded from the episode.

(iv) Items and services for acute clinical conditions not arising from existing, episode-related chronic clinical conditions or complications of LEJR surgery would be excluded from the episode.

(v) PBPM payments under CMS models determined to be primarily used for care coordination or care management services for clinical conditions in excluded categories of diagnoses, as described in § 510.200(d), would be excluded from the episode.

(4) CMS posts the following to the CMS Web site:

(i) Potential revisions to the exclusion to allow for public comment; and

(ii) An updated exclusions list after consideration of public comment.

#### § 510.205 Beneficiary inclusion criteria.

(a) Episodes tested in the CJR model include only those in which care is furnished to beneficiaries who meet all of the following criteria upon admission to the anchor hospitalization:

(1) Are enrolled in Medicare Parts A and Part B.

(2) Eligibility for Medicare is not on the basis of end stage renal disease, as described in § 406.13 of this chapter.

(3) Are not enrolled in any managed care plan (for example, Medicare Advantage, health care prepayment plans, or cost-based health maintenance organizations).

(4) Are not covered under a United Mine Workers of America health care plan.

(5) Have Medicare as their primary payer.

(b) If at any time during the episode a beneficiary no longer meets all of the criteria in this section, the episode is canceled in accordance with § 510.210(b).

#### § 510.210 Determination of the episode.

(a) *General.* The episode begins with the admission of a Medicare beneficiary described in § 510.205 to a participant hospital for an anchor hospitalization and ends on the 90th day after the date of discharge, with the day of discharge itself being counted as the first day in the 90-day post-discharge period.

(b) *Cancellation of an episode.* The episode is canceled and is not included in the determination of NPRA as specified in § 510.305 if the beneficiary does any of the following during the episode:

(1) Ceases to meet any criterion listed in § 510.205.

(2) Is readmitted to any participant hospital for another anchor hospitalization.

(3) Initiates an LEJR episode under BPCI.

(4) Dies.

### Subpart D—Pricing and Payment

#### § 510.300 Determination of episode target prices.

(a) *General.* CMS establishes episode target prices for participant hospitals for each performance year of the model as specified in this section. Episode target prices are established according to the following:

(1) MS–DRG assigned at discharge for anchor hospitalization and presence of hip fracture diagnosis for anchor hospitalization—

(i) MS–DRG 469 with hip fracture;

(ii) MS–DRG 469 without hip fracture;

(iii) MS–DRG 470 with hip fracture; or

(iv) MS–DRG 470 without hip fracture.

(2) *Applicable time period for performance year episode target prices.* Episode target prices are updated to account for Medicare payment updates no less than 2 times per year, for updated episode target prices effective October 1 and January 1, and at other intervals if necessary.

(3) *Episodes that straddle performance years or payment updates.* The episode target price that applies to the type of episode as of the date of admission for the anchor hospitalization is the episode target price that applies to the episode.

(4) Adjustments for quality performance, as specified in § 510.305(g).

(5) *Identifying episodes with hip fracture.* CMS develops a list of ICD–CM hip fracture diagnosis codes that, when reported in the principal diagnosis code files on the claim for the anchor hospitalization, represent a bone fracture for which a hip replacement procedure, either a partial hip arthroplasty or a total hip arthroplasty, could be the primary surgical treatment. The list of ICD–CM hip fracture diagnosis codes used to identify hip fracture episodes is posted on the CMS Web site.

(i) On an annual basis, or more frequently as needed, CMS updates the list of ICD–CM hip fracture diagnosis codes to reflect coding changes or other issues brought to CMS' attention.

(ii) CMS applies the following standards when revising the list of ICD–CM hip fracture diagnosis codes.

(A) The ICD–CM diagnosis code is sufficiently specific that it represents a bone fracture for which a physician could determine that a hip replacement procedure, either a PHA or a THA, could be the primary surgical treatment.

(B) The ICD–CM diagnosis code is the primary reason (that is, principal diagnosis code) for the anchor hospitalization.

(iii) CMS posts the following to the CMS Web site:

(A) Potential ICD–CM hip fracture diagnosis codes for public comment; and

(B) A final ICD–CM hip fracture diagnosis code list after consideration of public comment.

(b) *Episode target price.* (1) CMS calculates episode target prices based on a blend of each participant hospital's hospital-specific and regional episode expenditures. The region corresponds to the U.S. Census Division associated with the primary address of the CCN of the participant hospital and the regional component is based on all hospitals in said region, except as follows. In cases where an MSA selected for participation in CJR spans more than one U.S. Census Division, the entire MSA will be grouped into the U.S. Census Division where the largest city by population in the MSA is located for target price and reconciliation calculations. The calendar years used for historical expenditure calculations are as follows:

(i) Episodes beginning in 2012 through 2014 for performance years 1 and 2.

(ii) Episodes beginning in 2014 through 2016 for performance years 3 and 4.

(iii) Episodes beginning in 2016 through 2018 for performance year 5.

(2) Specifically, the blend consists of the following:

(i) Two-thirds of the participant hospital's own historical episode payments and one-third of the regional historical episode payments for performance years 1 and 2.

(ii) One-third of the hospital's own historical episode payments and two-thirds of the regional historical episode payments for performance year 3.

(iii) Regional historical episode payments for performance years 4 and 5.

(3) *Exception for low-volume hospitals.* Episode target prices for participant hospitals with fewer than 20 CJR episodes in total across the 3 historical years of data used to calculate the episode target price are based on 100 percent regional historical episode payments.

(4) *Exception for recently merged or split hospitals.* Hospital-specific historical episode payments for participant hospitals that have undergone a merger, consolidation, spin off or other reorganization that results in a new hospital entity without 3 full years of historical claims data are determined using the historical episode payments attributed to their predecessor(s).

(5) *Exception for high episode spending.* Episode payments are capped at 2 standard deviations above the mean regional episode payment for both the hospital-specific and regional components of the target price.

(6) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain incentive programs and add-on payments are excluded from historical episode payments by using the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

(7) *Communication of episode target prices.* CMS communicates episode target prices to participant hospitals before the performance period in which they apply.

(c) *Discount factor.* A participant hospital's episode target prices incorporate applicable discount factors to reflect Medicare's portion of reduced expenditures from the CJR model as described in this section.

(1) *Discount factor for reconciliation payments.* The applicable discount factor for reconciliation payments in all performance years is 3.0 percent.

(2) *Discount factors for repayment amounts.* The applicable discount factor for repayment amounts are—

(i) Not applicable in performance year 1, as the requirement for hospital repayment under the CJR model is waived in performance year 1;

(ii) In performance years 2 and 3, 2.0 percent; and

(3) *Discount factors affected by the quality incentive payment and composite performance years.* In all performance years, the discount factor may be affected by the quality incentive payment and composite quality score as provided in § 510.315 to create a different effective discount factor used for calculating reconciliation payments and repayment amounts.

(d) *Data sharing.* (1) CMS makes available to participant hospitals, through the most appropriate means, data that CMS determines may be useful to participant hospitals to do the following:

(i) Determine appropriate ways to increase the coordination of care.

(ii) Improve quality.

(iii) Enhance efficiencies in the delivery of care.

(iv) Otherwise achieve the goals of the CJR model described in this section.

(2) *Beneficiary-identifiable data.* (i) CMS makes beneficiary-identifiable data available to a participant hospital in accordance with applicable privacy laws and only in response to the hospital's request for such data for a beneficiary who has been furnished a billable service by the participant hospital corresponding to the episode definitions for CJR.

(ii) The minimum data necessary to achieve the goals of the CJR model, as determined by CMS, may be provided under this section for a participant hospital's baseline period and no less frequently than on a quarterly basis throughout the hospital's participation in the CJR model.

**§ 510.305 Determination of the NPRA and reconciliation process.**

(a) *General.* Providers and suppliers furnishing items and services included in the episode bill for such items and services in accordance with existing rules and as if this part were not in effect.

(b) *Reconciliation.* CMS uses a series of reconciliation processes, which CMS performs as described in paragraphs (d) and (f) of this section after the end of each performance year, to establish final payment amounts to participant hospitals for CJR episodes for a given performance year. Following the end of each performance year, CMS determines actual episode payments for each episode for the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) and determines the amount of a reconciliation payment or repayment amount.

(c) *Data used.* CMS uses the most recent claims data available to perform each reconciliation calculation.

(d) *Annual reconciliation.* (1) Beginning 2 months after the end of each performance year, CMS performs a reconciliation calculation to establish an NPRA for each participant hospital.

(2) CMS—

(i) Calculates the NPRA for each participant hospital in accordance with paragraph (e) of this section including the adjustments provided for in paragraph (e)(1)(iv) of this section; and

(ii) Assesses whether hospitals meet specified quality requirements under § 510.315.

(e) *Calculation of the NPRA.* By comparing the episode target prices described in § 510.300 and the participant hospital's actual episode spending for the performance year and applying the adjustments in paragraph (e)(1)(v) of this section, CMS establishes an NPRA for each participant hospital for each performance year.

(1) *Initial calculation.* In calculating the NPRA for each participant hospital for each performance year, CMS does the following:

(i) Determines actual episode payments for each episode included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) using claims data that is available 2 months after the end of the performance year. Actual episode payments are capped at the amount determined in accordance with § 510.300(b)(5) for the performance year.

(ii) Multiplies each episode target price, after applying any reduction to the discount percentage as provided in § 510.315(f) by the number of episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)) to which that episode target price applies.

(iii) Aggregates the amounts computed in paragraph (e)(1)(ii) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 510.210(b)).

(iv) Subtracts the amount determined under paragraph (e)(1)(i) of this section from the amount determined under paragraph (e)(1)(iii) of this section.

(v) Makes the following adjustments:

(A) *Increases in post-episode spending.* If the average post-episode Medicare Parts A and B spending for a participant hospital in any given performance year is greater than 3 standard deviations above the regional average post-episode spending for the same performance year, then the spending amount exceeding three standard deviations above the regional average post-episode spending for the same performance year is applied to the NPRA.

(B) *Limitation on loss.* Except as provided in paragraph (e)(1)(v)(D) of this section, the total amount any participant hospital is responsible for repaying to Medicare for a performance year cannot exceed the following:

(*1*) For performance year 2 only, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*2*) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*3*) For performance years 4, and 5, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*4*) As provided in paragraph (h)(6)(i) of this section, the subsequent reconciliation calculation reassesses the limitation on loss for a given performance year by applying the limitations on loss to the aggregate of the 2 reconciliation calculations.

(C) *Limitation on gain.* The total amount of any reconciliation payment made to a participant hospital for a performance year cannot exceed the following:

(*1*) For performance years 1 and 2, 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*2*) For performance year 3, 10 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*3*) For performance years 4, and 5, 20 percent of the amount calculated in paragraph (e)(1)(iii) of this section for the performance year.

(*4*) As provided in paragraph (h)(6)(i) of this section, the subsequent reconciliation calculation reassesses the limitation on gain for a given performance year by applying the limitation on gain limits to the aggregate of the two reconciliation calculations.

(D) *Financial loss limits for rural hospitals, SCHs, MDHs, and RRCs.* If a participant hospital is a rural hospital, SCH, MDH or RRC, then for performance year 2, the total repayment amount for which the participant hospital is responsible cannot exceed 3 percent of the amount calculated in paragraph (e)(1)(iii) of this section. For performance years 3 through 5, the total repayment amount cannot exceed 5 percent of the amount calculated in paragraph (e)(1)(iii) of this section.

(f) *Determination of reconciliation or repayment amount*— (1) *Determination of the reconciliation or repayment amount.* (i) Subject to paragraph (f)(1)(iii) of this section, for performance year 1, the reconciliation payment (if any) is equal to the NPRA.

(ii) Subject to paragraph (f)(1)(iii) of this section, for performance years 2 through 5, results from the subsequent reconciliation calculation for a prior year's reconciliation, as described in paragraph (h)(6)(i) of this section, are applied to the current year's NPRA in order to determine the reconciliation or repayment amount.

(iii) The reconciliation or repayment amount may be adjusted as provided in § 510.410(b)(5).

(2) *Reconciliation payment.* If the amount described in paragraph (f)(1) of this section is positive and the composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 4.00), good (defined as greater than or equal to 6.0 and less than or equal to 13.2), or excellent (defined as greater than 13.2), Medicare pays the participant hospital a reconciliation payment in an amount equal to the amount described in paragraph (f)(1) of this section.

(3) *Repayment amount.* If the amount described in paragraph (f)(1) of this section is negative, the participant hospital pays to Medicare an amount equal to the amount described in paragraph (f)(1) of this section, in accordance with § 405.371 of this chapter. CMS waives this requirement for performance year 1.

(g) *Determination of eligibility for reconciliation based on quality.* (1) CMS assesses each participant hospital's performance on quality metrics, as described in § 510.315, to determine whether the participant hospital is eligible to receive a reconciliation payment for a performance year.

(2) If the hospital's composite quality score described in § 510.315 is acceptable (defined as greater than or equal to 4.00), good (defined as greater than or equal to 6.0 and less than or equal to 13.2), or excellent (defined as greater than 13.2), and the hospital is determined to have a positive NPRA under § 510.305(e)), the hospital is eligible for a reconciliation payment.

(3) If the hospital's composite quality score described in § 510.315 is below acceptable, defined as less than 4.00 for a performance year, the hospital is not eligible for a reconciliation payment.

(4) If the hospital is found to be engaged in an inappropriate and systemic under delivery of care, the quality of the care provided must be considered to be seriously compromised and the hospital must be ineligible to receive or retain a reconciliation payment for any period in which such under delivery of care was found to occur.

(h) *Reconciliation report.* CMS issues each participant hospital a CJR reconciliation report for the performance year. Each CJR reconciliation report contains the following:

(1) Information on the participant hospital's composite quality score described in § 510.315.

(2) The total actual episode payments for the participant hospital.

(3) The NPRA.

(4) Whether the participant hospital is eligible for a reconciliation payment or must make a repayment to Medicare.

(5) The NPRA and subsequent reconciliation calculation amount for the previous performance year, as applicable.

(6) The reconciliation payment or repayment amount.

(i) *Subsequent reconciliation calculation.* (A) Fourteen months after the end of each performance year, CMS performs an additional calculation, using claims data available at that time, to account for final claims run-out and any additional overlap between the CJR model and other CMS models and programs as described in paragraph (h)(6)(i)(B) of this section.

(B) The subsequent reconciliation calculation accounts for cases in which a portion of the CJR discount percentage is paid out to an ACO as shared savings by reducing the reconciliation payment amount for a CJR hospital, if available, by the amount of the discount percentage paid out to the ACO as shared savings. This adjustment is only made when the participant hospital is a participant or provider/supplier in the ACO and the beneficiary in the CJR episode is assigned to one of the following ACO models or program:

(*1*) The Pioneer ACO model.

(*2*) The Medicare Shared Savings Program.

(*3*) The Next Generation ACO model.

(*4*) The Comprehensive ESRD Care Initiative.

(C) The additional calculation occurs concurrently with the reconciliation process for the most recent performance year. If the result of the subsequent calculation is different than zero, CMS applies the stop-loss and stop-gain limits in paragraph (e) of this section to the calculations in aggregate for that performance year (the initial reconciliation and the subsequent calculation) to ensure the amount does not exceed the stop-loss or stop-gain limits. CMS then applies the subsequent calculation amount to the NPRA for the most recent performance year in order to determine the reconciliation amount or repayment amount for the most recent performance year. Because hospitals will not have financial repayment responsibility for performance year 1, for the performance year 2 reconciliation report only, the subsequent calculation amount (for performance year 1) is applied to the performance year 1 NPRA to ensure that the combined amount is not less than 0. If the combined performance year 1 NPRA and subsequent calculation for performance year 1 is less than 0, the subsequent calculation amount would be capped at the value that would result in a net amount of 0 for the combined performance year 1 NPRA and subsequent calculation.

**§ 510.310 Appeals process.**

(a) *Notice of calculation error (first level of appeal).* Subject to the limitations on review in subpart d of this part, if a participant hospital wishes to dispute the calculation that involves a matter related to payment, reconciliation amounts, repayment amounts, or determinations associated with quality measures affecting payment, the hospital is required to provide written notice of the error, in a form and manner specified by CMS.

(1) Unless the participant hospital provides such notice, the CJR reconciliation report is deemed final 45 calendar days after it is issued.

(2) If CMS receives a timely notice of a calculation error, CMS responds in writing within 30 calendar days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the participant hospital.

(3) If a participant hospital does not submit timely notice of a calculation error in accordance with the timelines and processes specified by CMS, then CMS deems final the CJR reconciliation report and proceeds with the payment or repayment processes, as applicable.

(4) Only participant hospitals may use the dispute resolution process described in this part.

(b) *Dispute resolution process (second level of appeal).* (1) If the participant hospital is dissatisfied with CMS's response to the notice of a calculation error, the participant hospital may request a reconsideration review in a form and manner as specified by CMS.

(2) The reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the participant hospital's assertion that CMS or its representatives did not accurately calculate the NPRA, the reconciliation payment, or the repayment amount in accordance with § 510.305.

(3) If CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the issue date of CMS's response to the participant hospital's notice of calculation error, then CMS's response to the calculation error is deemed final and CMS proceeds with reconciliation payment or repayment processes, as applicable, as described in § 510.305.

(4) A CMS reconsideration official notifies the participant hospital in writing within 15 calendar days of receiving the participant hospital's review request of the following:

(i) The date, time, and location of the review.

(ii) The issues in dispute.

(iii) The review procedures.

(iv) The procedures (including format and deadlines) for submission of evidence.

(5) The CMS reconsideration official takes all reasonable efforts to schedule the review to occur no later than 30 days after the date of receipt of the notification.

(6) The provisions at § 425.804(b), (c), and (e) of this chapter are applicable to reviews conducted in accordance with the reconsideration review process for CJR.

(7) The CMS reconsideration official issues a written determination within 30 days of the review. The determination is final and binding.

(c) *Exception to the process.* If the participant hospital contests a matter that does not involve an issue contained in, or a calculation which contributes to, a CJR reconciliation report, a notice of calculation error is not required. An example of such a matter is termination of the participant hospital from the model. In those instances, if CMS does not receive a request for reconsideration from the participant hospital within 10 calendar days of the notice of the initial determination, the initial determination is deemed final and CMS proceeds with action indicated in the initial determination.

(d) *Limitations on review.* In accordance with section 1115A(d)(2) of the Act, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

(1) The selection of models for testing or expansion under section 1115A of the Act.

(2) The selection of organizations, sites, or participants to test those models selected.

(3) The elements, parameters, scope, and duration of such models for testing or dissemination.

(4) Determinations regarding budget neutrality under section 1115A(b)(3) of Act.

(5) The termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of Act.

(6) Decisions about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not

expected to meet criteria described in paragraph (d)(1) or (2) of this section.

**§ 510.315 Composite quality scores for determining reconciliation payment eligibility and quality incentive payments.**

(a) *General.* A participant hospital's eligibility for a reconciliation payment under § 510.305(g), and the determination of quality incentive payments under paragraph (f) of this section, for a performance year depend on the hospital's composite quality score (including any quality performance points and quality improvement points earned) for that performance year.

(b) *Composite quality score.* CMS calculates a composite quality score for each participant hospital for each performance year, which equals the sum of the following:

(1) The hospital's quality performance points for the hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in § 510.400(a)(1). This measure is weighted at 50 percent of the composite quality score.

(2) The hospital's quality performance points for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.400(a)(2). This measure is weighted at 40 percent of the composite quality score.

(3) Any additional quality improvement points the hospital may earn as a result of demonstrating improvement on either or both of the quality measures in paragraphs (b)(1) and (2) of this section, as described in paragraph (d) of this section.

(4) If applicable, 2 additional points for successful THA/TKA voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 510.400(b). Successful submission is weighted at 10 percent of the composite quality score.

(c) *Quality performance points.* CMS computes quality performance points for each quality measure based on the participant hospital's performance percentile relative to the national distribution of all hospitals' performance on that measure.

(1) For the hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in § 510.400(a)(1), CMS assigns the participant hospital measure value to a performance percentile and then quality performance points are assigned based on the following performance percentile scale:

(i) 10.00 points for ≥90th.
(ii) 9.25 points for ≥80th and <90th.
(iii) 8.50 points for ≥70th and <80th;
(iv) 7.75 points for ≥60th and <70th.
(v) 7.00 points for ≥50th and <60th.
(vi) 6.25 points for ≥40th and <50th.
(vii) 5.50 points for ≥30th and <40th.
(ix) 0.0 points for <30th.

(2) For the Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.400(a)(2), CMS assigns the participant hospital measure value to a performance percentile and quality performance points are assigned based on the following performance percentile scale:

(i) 8.00 points for ≥90th.
(ii) 7.40 points for ≥80th and <90th.
(iii) 6.80 points for ≥70th and <80th.
(iv) 6.20 points for ≥60th and <70th.
(v) 5.60 points for ≥50th and <60th.
(vi) 5.00 points for ≥40th and <50th.
(vii) 4.40 points for ≥30th and <40th.
(ix) 0.0 points for <30th.

(d) *Quality improvement points.* If a participant hospital's quality performance percentile on an individual measure described in § 510.400(a) increases from the previous performance year by at least 3 deciles on the performance percentile scale, then the hospital is eligible to receive quality improvement points equal to 10 percent of the total available points for that individual measure.

(e) *Exception for hospitals without a measure value.* In the case of a participant hospital without a measure value that would allow CMS to assign quality performance points for that quality measure, CMS assigns the 50th percentile quality performance points to the hospital for the individual measure.

(1) A participant hospital will not have a measure value for the—

(i) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty measure (NQF #1550) described in § 510.400(a)(1) if the hospital does not meet the minimum 25 case count; or

(ii) Hospital Consumer Assessment of Healthcare Providers and Systems Survey measure (NQF #0166) described in § 510.400(a)(2) if the hospital does not meet the minimum of 100 completed survey and does not have 4 consecutive quarters of HCAHPS data.

(ii) For either of the measures described in paragraphs (e)(1) or (2) of this section, if CMS identifies an error in the data used to calculate the measure and suppresses the measure value.

(f) *Quality incentive payments.* CMS provides incentive payments to participant hospitals that demonstrate good or excellent quality performance on the composite quality scores described in paragraph (b) of this section. These incentive payments are implemented in the form of the following reductions to the applicable discount factors described in § 510.300(c):

(1) A 1.0 percentage point reduction to the applicable discount factor for participant hospitals with good quality performance, defined as composite quality scores that are greater than or equal to 6.0 and less than or equal to 13.2.

(2) A 1.5 percentage point reduction to the applicable discount factor for participant hospitals with excellent quality performance, defined as composite quality scores that are greater than 13.2.

**§ 510.320 Treatment of incentive programs or add-on payments under existing Medicare payment systems.**

The CJR model does not replace any existing Medicare incentive programs or add-on payments. The target price and NPRA for a participant hospital are independent of, and do not affect, any incentive programs or add-on payments under existing Medicare payment systems.

**§ 510.325 Allocation of payments for services that straddle the episode.**

(a) *General.* Services included in the episode that straddle the episode are prorated so that only the portion attributable to care furnished during the episode are included in the calculation of actual episode payments.

(b) *Proration of services.* Payments for services that straddle the episode are prorated using the following methodology:

(1) *Non-IPPS inpatient services and other inpatient services.* Non-IPPS inpatient services, and services furnished by other inpatient providers that extend beyond the end of the episode are prorated according to the percentage of the actual length of stay (in days) that falls within the episode.

(2) *Home health agency services.* Home health services paid under the prospective payment system in part 484, subpart E of this chapter are prorated according to the percentage of days, starting with the first billable service date (''start of care date'') and through and including the last billable service date, that occur during the episode. This methodology is applied in the same way if the home health services begin (the start of care date) prior to the start of the episode.

(3) *IPPS services.* IPPS claim amounts that extend beyond the end of the

episode are prorated according to the geometric mean length of stay, using the following methodology:

(i) The first day of the IPPS stay is counted as 2 days.

(ii) If the actual length of stay that occurred during the episode is equal to or greater than the MS–DRG geometric mean, the normal MS–DRG payment is fully allocated to the episode.

(iii) If the actual length of stay that occurred during the episode is less than the geometric mean, the normal MS–DRG payment amount is allocated to the episode based on the number of inpatient days that fall within the episode.

(iv) If the full amount is not allocated to the episode, any remainder amount is allocated to the post-episode spending calculation (defined in § 510.2).

## Subpart E—Quality Measures, Beneficiary Protections, and Compliance Enforcement

### § 510.400 Quality measures and reporting.

(a) *Reporting of quality measures.* The following quality measures are used for public reporting, for determining whether a participant hospital is eligible for reconciliation payments under § 510.305(g), and whether a participant hospital is eligible for quality incentive payments under § 510.315(f) in the performance year:

(1) Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty.

(2) Hospital Consumer Assessment of Healthcare Providers and Systems Survey.

(b) *Requirements for successful voluntary data submission of patient-reported outcomes and limited risk variable data.* To be eligible to receive the additional points added to the composite quality score for successful voluntary data submission of patient-reported outcomes and limited risk variable data, as described in § 510.315(b)(4), participant hospitals must submit the THA/TKA patient-reported outcome and limited risk variable data requested by CMS related to the pre- and post-operative periods for elective primary total hip and/or total knee arthroplasty procedures. The data must be submitted within 60 days of the end of the most recent performance period and be accompanied by the patient-reported outcomes and limited risk variable data (eleven elements finalized) as outlined in § 510.315(b)(4).

(1) For each eligible procedure all eleven risk variable data elements are required to be submitted. The eleven risk variables are as follows:

(i) Date of birth.

(ii) Race.

(iii) Ethnicity.

(iv) Date of admission to anchor hospitalization.

(v) Date of eligible THA/TKA procedure.

(vi) Medicare Health Insurance Claim Number.

(vii) Body mass index.

(viii) Use of chronic (≥90 day) narcotics.

(ix) Total painful joint count.

(x) Quantified spinal pain.

(xi) Single Item Health Literacy Screening (SILS2) questionnaire.

(2) Hospitals must also submit the amount of requested THA/TKA patient-reported outcomes data required for each year of the model in order to be considered successful in submitting voluntary data.

(i) The amount of requested THA/TKA patient-reported outcomes data to submit, in order to be considered successful will increase each subsequent year of the model over the 5 years of the model.

(ii) A phase-in approach that determines the amount of requested THA/TKA patient-reported outcomes data to submit over the 5 years of the program will be applied so that in year 1 successful submission of data would mean CMS received all requested THA/TKA patient-reported outcomes and limited risk variable data on both of the following:

(A) Greater than or equal to 50 percent of eligible procedures or greater than or equal to 50 eligible patients during the data collection period.

(B) Submission of requested THA/TKA PRO and limited risk variable data is completed within 60 days of the most recent performance period.

(3) For years 1 through 5 of the model an increasing amount of data is requested by CMS for each performance period as follows:

(i) Year 1 (2016). Submit pre-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 and August 31, 2016, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(ii) Year 2 (2017). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥50% or ≥50 eligible procedures performed between July 1, 2016 through August 31, 2016; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 through June 30, 2017, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(iii) Year 3 (2018). Submit—

(A) POST-operative data on primary elective THA/TKA procedures for ≥60% or ≥75 procedures performed between September 1, 2016 and June 30, 2017; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(iv) Year 4 (2019). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥70% or ≥100 procedures performed between July 1, 2017 and June 30, 2018; and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(v) Year 5 (2020). Submit—

(A) Post-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2018 and June 30, 2019 and

(B) Pre-operative data on primary elective THA/TKA procedures for ≥80% or ≥200 procedures performed between July 1, 2019 and June 30, 2020, unless CMS requests a more limited data set, in which case, submit all requested data elements.

(c) *Public reporting.* CMS—

(1) Makes the quality measurement results calculated for the complication and patient survey quality measures described in paragraph (a) of this section for each participant hospital in each performance year publicly available on the CMS Web site in a form and manner as determined by CMS;

(2) Shares each participant hospital's quality metrics with the hospital prior to display on the Web site; and

(3) Does not publicly report the voluntary patient-reported outcomes and limited risk variable data during this model, but does indicate whether a hospital has voluntarily submitted such data.

### § 510.405 Beneficiary choice and beneficiary notification.

(a) *Beneficiary choice.* The CJR model does not restrict Medicare beneficiaries' ability to choose any Medicare enrolled provider or supplier, or any physician or practitioner who has opted out of Medicare.

(1) As part of discharge planning and referral, participant hospitals must inform beneficiaries of all Medicare participating post-acute care providers in an area and must identify those post-acute care providers with whom they have sharing arrangements. Participant hospitals may recommend preferred providers and suppliers, consistent with applicable statutes and regulations. Participant hospitals may not limit beneficiary choice to any list of providers or suppliers in any manner other than that permitted under applicable statutes and regulations. Participant hospitals must respect patient and family preferences when they are expressed.

(2) Participant hospitals may not charge any CJR collaborator a fee to be included on any list of preferred providers or suppliers, nor may the participant hospital accept such payments.

(b) *Required beneficiary notification*—(1) *Hospital detailed notification.* Each participant hospital must provide written notice to any Medicare beneficiary that meets the criteria in § 510.205 of his or her inclusion in the CJR model. The notice must be upon admission to the participant hospital or immediately following the decision to schedule an LEJR surgery, whichever occurs later. The beneficiary notification must contain all of the following:

(i) A detailed explanation of the model and how it might be expected to affect the beneficiary's care.

(ii) Notification that the beneficiary retains freedom of choice to choose providers and services.

(iii) Explanation of how patients can access care records and claims data through an available patient portal, and how they can share access to their Blue Button® electronic health information with caregivers.

(iv) A statement that all existing Medicare beneficiary protections continue to be available to the beneficiary. These include the ability to report concerns of substandard care to Quality Improvement Organizations and 1–800–MEDICARE.

(v) A list of the providers and suppliers with whom the participant hospital has a collaborator agreement.

(2) *Physician provision of notice.* A participant hospital must require any physician that is a CJR collaborator to provide written notice of the structure of the model and the existence of the physician's sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. The notice must be provided at the time that the decision to undergo LEJR surgery is made.

(3) *PAC provider/supplier notification.* A participant hospital must require any provider or supplier, other than the treating physician discussed in paragraph (b)(2) of this section, with whom it has executed a collaborator agreement to provide written notice of the existence of its sharing arrangement with the participant hospital to any Medicare beneficiary that meets the criteria specified in § 510.205. The notice must be provided no later than the time at which the beneficiary first receives services from the provider or supplier during the CJR episode.

(4) *Discharge planning notice.* A participant hospital must provide the beneficiary with a written notice of any potential financial liability, associated with non-covered services recommended or presented as an option as part of discharge planning, no later than the time that the beneficiary discusses a particular PAC option or at the time the beneficiary is discharged, whichever occurs earlier.

(i) If the hospital knows or should have known that the beneficiary is considering or has decided to receive a non-covered post-acute service or other non-covered associated service or supply, the hospital must notify the beneficiary that the service would not be covered by Medicare.

(ii) If the hospital is discharging a beneficiary to a SNF prior to the occurrence of a 3 day hospital stay, and the beneficiary is being transferred to or is considering a SNF that would not qualify under the SNF 3-day waiver in § 510.610, the hospital notify the beneficiary in accordance with paragraph (b)(4)(i) of this section that the beneficiary will be responsible for costs associated with that stay except those which would be covered by Medicare Part B during a non-covered inpatient SNF stay.

**§ 510.410 Compliance enforcement.**

(a) *General.* Participant hospitals must comply with all of the requirements outlined in this part. Except as specifically noted in this part, the regulations under this part must not be construed to affect the payment, coverage, program integrity, or other requirements (such as those in parts 412 and 482 of this chapter) that apply to providers and suppliers under this chapter.

(b) *Failure to comply.* (1) CMS may take one or more of the remedial actions set forth in paragraph (b)(2) of this section if a participant hospital or any of the participant hospital's CJR collaborators—

(i) Fails to comply with any applicable requirements of this part or is identified as noncompliant through monitoring by HHS (including CMS and OIG) of the CJR model, including but not limited to the following:

(A) Avoiding potentially high cost patients.

(B) Targeting potentially low cost patients.

(C) Failing to provide medically appropriate services or systematically engaging in the over or under delivery of appropriate care.

(D) Failing to provide beneficiaries with complete and accurate information, including required notices.

(E) Failing to allow beneficiary choice of medically necessary options, including non-surgical options.

(F) Failing to follow the requirements related to collaborator agreements;

(ii) Has signed a collaborator agreement with a CJR collaborator if the agreement is noncompliant with the requirements of this part;

(iii) Takes any action that threatens the health or safety of patients;

(iv) Avoids at-risk Medicare beneficiaries, as this term is defined in § 425.20;

(v) Avoids patients on the basis of payer status;

(vi) Is subject to sanctions or final actions of an accrediting organization or federal, state, or local government agency that could lead to the inability to comply with the requirements and provisions of this part;

(vii) Takes any action that CMS determines for program integrity reasons is not in the best interests of the CJR model, or fails to take any action that CMS determines for program integrity reasons should have been taken to further the best interests of the CJR model;

(viii) Is subject to action by HHS (including OIG and CMS) or the Department of Justice to redress an allegation of fraud or significant misconduct, including intervening in a False Claims Act qui tam matter, issuing a pre-demand or demand letter under a civil sanction authority, or similar actions; or

(ix) Is subject to action involving violations of the physician self-referral law, civil monetary penalties law, federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to the CJR model.

(2) Remedial actions include the following:

(i) Issue a warning letter to the participant hospital.

(ii) Require the participant hospital to develop a corrective action plan, commonly referred to as a CAP.

(iii) Reduce or eliminate a participant hospital's reconciliation payment.

(iv) Require a participant hospital to terminate a collaborator agreement with a CJR collaborator and prohibit further engagement in the CJR model by that CJR collaborator.

(v) Terminate the participant hospital's participation in the CJR model.

(3) CMS may add 25 percent to a repayment amount on a participant hospital's reconciliation report if all of the following criteria are satisfied:

(i) CMS has required a corrective action plan from a participant hospital.

(ii) The participant hospital is not due a positive reconciliation payment but instead owes a repayment amount to CMS.

(iii) The participant hospital fails to timely comply with the corrective action plan or is noncompliant with the model's requirements.

## Subpart F—Financial Arrangements and Beneficiary Incentives

### § 510.500 Financial arrangements under the CJR model.

(a) *General.* (1) A participant hospital may elect to enter into sharing arrangements.

(2) A participant hospital must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. Any gainsharing payments or alignment payments made in accordance with a sharing arrangement must be made only from the participant hospital to the CJR collaborator with whom the participant hospital has signed a collaborator agreement containing a sharing arrangement.

(3) CMS may review any sharing arrangement for compliance with the requirements of this part and to ensure that it does not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care.

(4) The participant hospital has ultimate responsibility for fully complying with all provisions of the CJR model.

(5) If a participant hospital enters into a sharing arrangement, it must update its compliance program to include oversight of sharing arrangements and compliance with the requirements of the CJR model.

(6) The board or other governing body of the participant hospital must have responsibility for overseeing the participant hospital's participation in the CJR model, its arrangements with CJR collaborators, its payment of gainsharing payments and receipt of alignment payments, and its use of beneficiary incentives in the CJR model.

(7) Participant hospitals must develop and maintain a written set of policies for selecting providers and suppliers for sharing gains and risk as CJR collaborators. This set of policies must contain criteria for selection of CJR collaborators related to, and inclusive of, the quality of care to be delivered by the CJR collaborator to beneficiaries during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator. All collaborator agreements must require the CJR collaborator to have met, or agree to meet, the quality criteria for selection.

(b) *Sharing arrangement requirements.* Each sharing arrangement must comply with the following criteria:

(1) The sharing arrangement must be set forth in a collaborator agreement that complies with the requirements of paragraph (c) of this section.

(2) The sharing arrangement must comply with all relevant laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements.

(3) An individual or entity's participation in a sharing arrangement must be voluntary and without penalty for nonparticipation.

(4) The parties must enter into a sharing arrangement before care is furnished to CJR beneficiaries under the terms of the sharing arrangement.

(5)(i) To be eligible to receive a gainsharing payment, a CJR collaborator must meet quality criteria for the calendar year for which the gainsharing payment is determined by the participant hospital. The quality criteria must be established by the participant hospital and directly related to CJR episodes of care.

(ii) To be eligible to receive a gainsharing payment or make an alignment payment, a CJR collaborator other than a PGP must directly furnish a billable service to a CJR beneficiary during a CJR episode that occurred in the calendar year in which the savings or loss was created.

(iii) To be eligible to receive a gainsharing payment, a PGP that is a CJR collaborator must meet the following criteria:

(A) The PGP must have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participant hospital's internal cost savings was generated, or to which the NPRA applied, the latter of which is contained in a reconciliation payment.

(B) The PGP must contribute to a participant hospital's care redesign in the CJR model and be clinically involved in the care of CJR beneficiaries. The following is a non-exhaustive list of ways in which a PGP might be clinically involved in the care of CJR beneficiaries:

(*1*) Provide care coordination services to CJR beneficiaries during and/or after inpatient admission.

(*2*) Engage with a participant hospital in care redesign strategies, and actually perform a role in implementing such strategies, that are designed to improve the quality of care for LEJR episodes and reduce the LEJR episode spending.

(*3*) In coordination with other providers and suppliers (such as members of the PGP, participant hospitals, post-acute care providers), implement strategies designed to address and manage the comorbidities of CJR beneficiaries.

(6) No entity or individual, whether a party to a collaborator agreement or not, may condition the opportunity to make or receive gainsharing payments or to make or receive alignment payments on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(7) Gainsharing payments, if any, must be—

(i) Derived solely from reconciliation payments, or internal cost savings, or both;

(ii) Actually and proportionally related to the care of beneficiaries in a CJR episode;

(iii) Distributed on an annual basis (not more than once per calendar year);

(iv) Not be a loan, advance payments, or payments for referrals or other business; and

(v) Be clearly identified and comply with all provisions in this part, as well as all applicable laws, statutes, and rules.

(8) Alignment payments from a CJR collaborator to a participant hospital may be made at any interval that is agreed upon by both parties, and must—

(i) Not be issued, distributed, or paid prior to the calculation by CMS of a repayment amount reflected in a reconciliation report; and

(ii) Not be a loan, advance payments, or payments for referrals or other business.

(9) A participant hospital must not make a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with this part or the fraud and abuse laws, or for the

provision of substandard care in CJR episodes or other integrity problems.

(10) In a calendar year, the aggregate amount of all gainsharing payments distributed by a participant hospital that are derived from a CJR reconciliation payment may not exceed the amount of the reconciliation payment the participant hospital receives from CMS.

(11) In a calendar year, the aggregate amount of all alignment payments received by the participant hospital must not exceed 50 percent of the participant hospital's repayment amount. No alignment payments may be collected by a participant hospital if it does not owe a repayment amount.

(12) The aggregate amount of all alignment payments from any one CJR collaborator to a participant hospital must not be greater than 25 percent of the participant hospital's repayment amount.

(13) A sharing arrangement must not induce the participant hospital, CJR collaborator, or any employees or contractors of the participant hospital or CJR collaborator to reduce or limit medically necessary services to any Medicare beneficiary.

(14) A sharing arrangement must not restrict the ability of a CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

(15) The methodology for determining gainsharing payments must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(16) The methodology for determining alignment payments must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(17) The total amount of a gainsharing payment for a calendar year paid to an individual physician or nonphysician practitioner who is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule (PFS) for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner.

(18) The total amount of gainsharing payments for a calendar year paid to a PGP that is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for services that are billed by the PGP and furnished during a calendar year by members of the PGP to the participant hospital's CJR beneficiaries during CJR episodes.

(19) The participant hospital's determination of internal cost savings must satisfy the following criteria:

(i) Internal cost savings are calculated in accordance with generally accepted accounting principles and Government Auditing Standards (The Yellow Book).

(ii) All amounts determined to be internal cost savings must reflect actual, internal cost savings achieved by the participant hospital through implementation of care redesign elements identified and documented by the participant hospital. Internal cost savings does not include savings realized by any individual or entity that is not the participant hospital.

(iii) Internal cost savings may not reflect ''paper'' savings from accounting conventions or past investment in fixed costs.

(20) All gainsharing payments and any alignment payments must meet the requirements set forth in this section and be administered by the participant hospital in accordance with generally accepted accounting principles. In no event may the participant hospital receive any amounts from a CJR collaborator under a sharing arrangement that are not alignment payments.

(21) All gainsharing payments and alignment payments must be made through EFT.

(c) *Contents of collaborator agreement.* Each collaborator agreement must satisfy the following criteria:

(1) The collaborator agreement must contain a description of the sharing arrangement between the participant hospital and the CJR collaborator regarding gainsharing payments and alignment payments. This description must specify the following:

(i) The parties to the sharing arrangement.

(ii) The date of the sharing arrangement.

(iii) The purpose and scope of the sharing arrangement.

(iv) The financial or economic terms of the sharing arrangement, including the frequency of payment, and the methodology and accounting formula for determining the amount of any gainsharing payment or alignment payment.

(v) Safeguards to ensure that alignment payments are made solely for purposes related to sharing responsibility for funds needed to repay Medicare in the CJR model.

(vi) Plans regarding care redesign.

(vii) Changes in care coordination or delivery that is applied to the participant hospital or CJR collaborators or both.

(viii) A description of how success will be measured.

(ix) Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out changes to care under the CJR model.

(2) The collaborator agreement must contain a requirement that the CJR collaborator and its employees and contractors must comply with the applicable provisions of this part (including requirements regarding beneficiary notifications, access to records, record retention, and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees) and all other applicable laws and regulations.

(3) The collaborator agreement must require the CJR collaborator to be in compliance with all Medicare provider enrollment requirements at § 424.500 of this chapter, including having a valid and active TIN or NPI, during the term of the agreement.

(4) The collaborator agreement must require the CJR collaborator to have a compliance program that includes oversight of the collaborator agreement and compliance with the requirements of the CJR model.

(5) The collaborator agreement must set forth a specific methodology for accruing, calculating, and verifying the internal cost savings generated by the participant hospital based on the care redesign elements specifically associated with the particular CJR collaborator.

(i) The methodology must set out the specific care redesign elements to be undertaken by the participant hospital or the CJR collaborator or both.

(ii) The methodology must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to CJR beneficiaries during an episode and must not directly account for the volume or value of referrals or business otherwise generated by, between or among the participant hospital, CJR collaborators, and any individual or entity affiliated with a participant hospital or CJR collaborator.

(iii) The specific methodologies for accruing and calculating internal cost savings must be transparent, measurable, and verifiable in accordance with generally accepted

accounting principles and Government Auditing Standards (The Yellow Book).

(6) The collaborator agreement must set forth the quality criteria established by the participant hospital that will be used in determining the gainsharing payment.

(7) The collaborator agreement must require the participant hospital to recoup gainsharing payments paid to CJR collaborators if gainsharing payments contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

(d) *Documentation requirements.* (1) Documentation of any collaborator agreement containing a sharing arrangement must be contemporaneous with the establishment of the arrangement.

(2) A participant hospital must maintain accurate current and historical lists of all CJR collaborators, including names and addresses of each CJR collaborator. The participant hospital must update the lists on at least a quarterly basis and publicly report the current and historical lists of CJR collaborators on a public-facing Web page on the participant hospital's Web site.

(3) The participant hospital and CJR collaborator must maintain contemporaneous documentation of the payment or receipt of any gainsharing payment or alignment payment. The documentation must identify at least the following: The nature of the payment (gainsharing payment or alignment payment); the identity of the parties making and receiving the payment; the date of the payment; the amount of the payment; and the date and amount of any recoupment of all or a portion of a CJR collaborator's gainsharing payment.

(4) The participant hospital must keep records of the following:

(i) Its process for determining and verifying the eligibility of CJR collaborators to participate in Medicare.

(ii) Information confirming the organizational readiness of the participant hospital to measure and track internal cost savings.

(iii) The participant hospital's plan to track internal cost savings.

(iv) Information on the accounting systems used to track internal cost savings.

(v) A description of current health information technology, including systems to track reconciliation payments and internal cost savings.

(vi) The participant hospital's plan to track gainsharing payments and alignment payments.

(vii) Whether the participant hospital recouped any gainsharing payments received by a CJR collaborator that contain funds derived from a CMS overpayment on a reconciliation report, or were based on the submission of false or fraudulent data.

(e) *Access to records and record retention.* All participant hospitals and CJR collaborators who enter into sharing arrangements must:

(1) Provide to CMS, the OIG, and the Comptroller General or their designees scheduled and unscheduled access to all books, contracts, records, documents, and other evidence (including data related to utilization and payments, quality criteria, billings, lists of CJR collaborators, sharing arrangements, and distribution arrangements, and the documentation required under paragraph (d) of this section) sufficient to enable the audit, evaluation, inspection, or investigation of the individual's or entity's compliance with CJR requirements, the quality of services furnished, the obligation to repay any reconciliation payments owed to CMS, or the calculation, distribution, receipt, or recoupment of gainsharing payments, alignment payments, or distribution payments.

(2) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital at least 30 calendar days before the normal disposition date; or

(ii) There has been a dispute or allegation of fraud or similar fault against the participant hospital or any CJR collaborator, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

### § 510.505 Distribution arrangements.

(a) *General.* (1) A PGP that has entered into a collaborator agreement with a participant hospital may distribute all or a portion of any gainsharing payment it receives from the hospital only in accordance with a distribution arrangement.

(2) All distribution arrangements must comply with the provisions of paragraph (b) of this section and all applicable laws and regulations, including the fraud and abuse laws.

(b) *Requirements.* (1) All distribution arrangements must be in writing and signed by the PGP and practice collaboration agent.

(2) Participation in a distribution arrangement must be voluntary and without penalty for nonparticipation.

(3) The distribution arrangement must require the practice collaboration agent to comply with the requirements set forth in this part.

(4) The opportunity to receive a distribution payment must not be conditioned directly or indirectly on the volume or value of referrals or business otherwise generated by, between or among the participant hospital, PGP, other CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.

(5) Methodologies for determining distribution payments must not directly account for volume or value of referrals, or business otherwise generated, by, between or among the participant hospital, PGP, other CJR collaborators, practice collaboration agents, and any individual or entity affiliated with a participant hospital, CJR collaborator, or practice collaboration agent.

(6) A practice collaboration agent is eligible to receive a distribution payment only if the PGP billed for an item or service furnished by the practice collaboration agent to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participating hospital accrued the internal cost savings or earned the reconciliation payment that comprise the gainsharing payment made to the PGP.

(7) When a PGP receives a gainsharing payment from a participant hospital in accordance with a sharing arrangement, all monies contained in such a gainsharing payment must be shared only with the physician or nonphysician practitioners that are PGP members that furnished a service to a CJR beneficiary during an episode of care in the calendar year from which the NPRA, as that term is defined in this part, or internal cost savings was generated, either or both of which are the only permitted sources of funds for a gainsharing payment.

(8) The total amount of distribution payments for a calendar year paid to a practice collaboration agent must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for services billed by the PGP and furnished by the practice collaboration agent to the participant hospital's CJR beneficiaries during a CJR episode.

(9) With respect to the distribution of any gainsharing payment received by a

PGP, the total amount of all distribution payments must not exceed the amount of the gainsharing payment.

(10) All distribution payments must be made through EFT.

(11) The practice collaboration agents must retain their ability to make decisions in the best interests of the patient, including the selection of devices, supplies, and treatments.

(12) The distribution arrangement must not—

(i) Induce a practice collaboration agent to reduce or limit medically necessary services to any Medicare beneficiary; or

(ii) Reward the provision of items and services that are medically unnecessary.

(13) The PGP must maintain contemporaneous documentation regarding distribution arrangements in accordance with § 510.500(e), including the relevant written agreements, the date and amount of any distribution payment, the identity of each practice collaboration agent who received a distribution payment, and a description of the methodology and accounting formula for determining the amount of any distribution payment.

(14) The PGP may not enter into a distribution arrangement with any member of the PGP that has a collaborator agreement in effect with a participant hospital.

**§ 510.510 Enforcement authority.**

(a) *OIG authority.* OIG authority is not limited or restricted by the provisions of the CJR model, including the authority to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

(b) *Other authorities.* None of the provisions of the CJR model limits or restricts the authority of any other government agency permitted by law to audit, evaluate, investigate, or inspect the participant hospital, CJR collaborators, or any other person or entity or their records, data, or information, without limitation.

**§ 510.515 Beneficiary incentives under the CJR model.**

(a) *General.* Participant hospitals may choose to provide in-kind patient engagement incentives to beneficiaries in a CJR episode, subject to the following conditions:

(1) The incentive must be provided directly by the participant hospital or by an agent of the hospital under the hospital's direction and control to the beneficiary during a CJR episode of care.

(2) The item or service provided must be reasonably connected to medical care provided to a beneficiary during an episode.

(3) The item or service must be a preventive care item or service or an item or service that advances a clinical goal, as listed in paragraph (b) of this section, for a beneficiary in a CJR episode by engaging the beneficiary in better managing his or her own health.

(4) The item or service must not be tied to the receipt of items or services outside the CJR episode of care.

(5) The item or service must not be tied to the receipt of items or services from a particular provider or supplier.

(6) The availability of the items or services must not be advertised or promoted except that a beneficiary may be made aware of the availability of the items or services at the time the beneficiary could reasonably benefit from them.

(7) The cost of the items or services must not be shifted to another federal health care program, as defined at section 1128B(f) of the Act.

(b) *Goals of the CJR model.* The following are the particular clinical goals of the CJR model, which may be advanced through beneficiary incentives:

(1) Beneficiary adherence to drug regimens.

(2) Beneficiary adherence to a care plan.

(3) Reduction of readmissions and complications resulting from LEJR procedures.

(4) Management of chronic diseases and conditions that may be affected by the lower extremity joint replacement procedure.

(c) *Documentation of beneficiary incentives.* (1) Participant hospitals must maintain documentation of items and services furnished as beneficiary incentives that exceed $25 in retail value.

(2) The documentation must be contemporaneous with the provision of the items and services and must include at least the following:

(i) The date the incentive is provided.

(ii) The identity of the beneficiary to whom the item or service was provided.

(3) The participant hospital must retain the required documentation in accordance with paragraph (e) of this section.

(d) *Technology provided to a beneficiary.* (1) Items or services involving technology provided to a beneficiary may not exceed $1,000 in retail value for any one beneficiary in any one CJR episode.

(2) Items or services involving technology provided to a beneficiary must be the minimum necessary to advance a clinical goal, as listed in paragraph (b) of this section, for a beneficiary in a CJR episode.

(3) Items of technology exceeding $100 in retail value must—

(i) Remain the property of the participant hospital; and

(ii) Be retrieved from the beneficiary at the end of the CJR episode. The participant hospital must document all retrieval attempts, including the ultimate date of retrieval. Documented, diligent, good faith attempts to retrieve items of technology will be deemed to meet the retrieval requirement.

(e) *Documentation and maintenance of records.* All participant hospitals that provide in-kind patient engagement incentives to beneficiaries in CJR episodes must:

(1) Provide to CMS, the OIG, and the Comptroller General or their designee(s) scheduled and unscheduled access to all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the participant hospital's compliance with CJR requirements for beneficiary incentives.

(2) Maintain all such books, contracts, records, documents, and other evidence for a period of 10 years from the last day of the participant hospital's participation in the CJR model or from the date of completion of any audit, evaluation, inspection, or investigation, whichever is later, unless—

(i) CMS determines that there is a special need to retain a particular record or group of records for a longer period and notifies the participant hospital at least 30 calendar days before the normal disposition rate; or

(ii) There has been a dispute or allegation of fraud or similar fault against the participant hospital, in which case the records must be maintained for an additional 6 years from the date of any resulting final resolution of the dispute or allegation of fraud or similar fault.

## Subpart G—Waivers

**§ 510.600 Waiver of direct supervision requirement for certain post-discharge home visits.**

(a) *General.* CMS waives the requirement in § 410.26(b)(5) of this chapter that services and supplies furnished incident to a physician's service must be furnished under the direct supervision of the physician (or other practitioner) to permit home visits as specified in this section. The services furnished under this waiver are not considered to be ''hospital services,'' even when furnished by the clinical staff of the hospital.

(b) *General supervision of qualified personnel.* The waiver of the direct

supervision requirement in § 410.26(b)(5) of this chapter applies only in the following circumstances:

(1) The home visit is furnished during the episode to a beneficiary who has been discharged from an anchor hospitalization.

(2) The home visit is furnished at the beneficiary's home or place of residence.

(3) The beneficiary does not qualify for home health services under sections 1835(a) and 1814(a) of the Act at the time of any such home visit.

(4) The visit is furnished by clinical staff under the general supervision of a physician or non-physician practitioner. Clinical staff are individuals who work under the supervision of a physician or other qualified health care professional, and who are allowed by law, regulation, and facility policy to perform or assist in the performance of a specific professional service, but do not individually report that professional service.

(5) No more than 9 visits are furnished to the beneficiary during the episode.

(c) *Payment.* Up to 9 post-discharge home visits per CJR episode may be billed under Part B by the physician or nonphysician practitioner or by the participant hospital to which the supervising physician has reassigned his or her billing rights.

(d) *Other requirements.* All other Medicare rules for coverage and payment of services incident to a physician's service continue to apply.

**§ 510.605 Waiver of certain telehealth requirements.**

(a) *Waiver of the geographic site requirements.* Except for the geographic site requirements for a face-to-face encounter for home health certification, CMS waives the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act for episodes being tested in the CJR model, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the episode in accordance with § 510.200(b).

(b) *Waiver of the originating site requirements.* Except for the originating site requirements for a face-to-face encounter for home health certification, CMS waives the originating site requirements under section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act for episodes being tested in the CJR model to permit a telehealth visit to originate in the beneficiary's home or place of residence, but only for services that—

(1) May be furnished via telehealth under existing requirements; and

(2) Are included in the CJR episode in accordance with § 510.200(b).

(c) *Waiver of selected payment provisions.* (1) CMS waives the payment requirements under section 1834(m)(2)(A) so that the facility fee normally paid by Medicare to an originating site for a telehealth service is not paid if the service is originated in the beneficiary's home or place of residence.

(2) CMS waives the payment requirements under section 1834(m)(2)(B) to allow the distant site payment for telehealth home visit HCPCS codes unique to this model to more accurately reflect the resources involved in furnishing these services in the home by basing payment upon the comparable office visit relative value units for work and malpractice under the Physician Fee Schedule.

(d) *Other requirements.* All other requirements for Medicare coverage and payment of telehealth services continue to apply, including the list of specific services approved to be furnished by telehealth.

**§ 510.610 Waiver of SNF 3-day rule.**

(a) *Waiver of the SNF 3-day rule.* For episodes being tested in the CJR model in performance years 2 through 5, CMS waives the SNF 3-day rule for coverage of a SNF stay for a CJR beneficiary following the anchor hospitalization, but only if the SNF is identified on the applicable calendar quarter list of qualified SNFs at the time of CJR beneficiary admission to the SNF.

(1) CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare Web site. Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months.

(2) CMS posts to the CMS Web site the list of qualified SNFs in advance of the calendar quarter and the waiver only applies for a beneficiary who has been discharged from an anchor hospitalization if the SNF is included on the applicable calendar quarter list for the date of the beneficiary's admission to the SNF.

(b) *Other requirements.* All other Medicare rules for coverage and payment of Part A-covered SNF services continue to apply.

**§ 510.615 Waiver of certain post-operative billing restrictions.**

(a) *Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period.* CMS waives the billing requirements for global surgeries to allow the separate billing of certain post-discharge home visits described under § 510.600, including those related to recovery from the surgery, as described in paragraph (b) of this section, for episodes being tested in the CJR model.

(b) *Services to which the waiver applies.* Up to 9 post-discharge home visits, including those related to recovery from the surgery, per CJR episode may be billed separately under Part B by the physician or nonphysician practitioner, or by the participant hospital to which the physician or nonphysician practitioner has reassigned his or her billing rights.

(c) *Other requirements.* All other Medicare rules for global surgery billing during the 90-day post-operative period continue to apply.

**§ 510.620 Waiver of deductible and coinsurance that otherwise apply to reconciliation payments or repayments.**

(a) *Waiver of deductible and coinsurance.* CMS waives the requirements of sections 1813 and 1822(a) of the Act for Medicare Part A and Part B payment systems only to the extent necessary to make reconciliation payments or receive repayments based on the NPRA that reflect the episode payment methodology under the final payment model for CJR participant hospitals.

(b) *Reconciliation payments or repayments.* Reconciliation payments or repayments do not affect the beneficiary cost-sharing amounts for the Part A and Part B services provided under the CJR model.

## Subparts H–J [Reserved]

## Subpart K—Model Termination

**§ 510.900. Termination of the CJR model.**

CMS may terminate the CJR model for reasons including but not limited to the following:

(a) CMS determines that it no longer has the funds to support the CJR model.

(b) CMS terminates the model in accordance with section 1115A(b)(3)(B) of the Act. As provided by section 1115A(d)(2) of the Act, termination of the model is not subject to administrative or judicial review.

Dated: November 2, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Dated: November 9, 2015.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

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