DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

[CMS–5524–F and IFC]

RIN 0938–AT16

Medicare Program; Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model: Extreme and Uncontrollable Circumstances Policy for the Comprehensive Care for Joint Replacement Payment Model

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

ACTION: Final rule; interim final rule with comment period.

SUMMARY: This final rule cancels the Episode Payment Models (EPMs) and Cardiac Rehabilitation (CR) Incentive Payment Model and rescinds the regulations governing these models. It also implements certain revisions to the Comprehensive Care for Joint Replacement (CJR) model, including: Giving certain hospitals selected for participation in the CJR model a one-time option to choose whether to continue their participation in the model; technical refinements and clarifications for certain payment, reconciliation and quality provisions; and a change to increase the pool of eligible clinicians that qualify as affiliated practitioners under the Advanced Alternative Payment Model (Advanced APM) track. An interim final rule with comment period is being issued in conjunction with this final rule in order to address the need for a policy to provide some flexibility in the determination of episode costs for providers located in areas impacted by extreme and uncontrollable circumstances.

DATES: *Effective Date:* These final and interim final regulations are effective on January 1, 2018.

Comment Period: To be assured consideration, comments on the interim final rule with comment period presented in section III. of this document must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on January 30, 2018.

FOR FURTHER INFORMATION CONTACT: Nora Fleming, (410) 786–6908.

For questions related to the CJR model: *CJR@cms.hhs.gov*.

For questions related to the EPMs: *EPMRULE@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The purpose of this final rule is to finalize our proposal to cancel the Episode Payment Models (EPMs) and the Cardiac Rehabilitation (CR) Incentive Payment Model, established by the Center for Medicare and Medicaid Innovation (Innovation Center) under the authority of section 1115A of the Social Security Act (the Act) and to rescind the regulations at 42 CFR part 512. Additionally, this final rule finalizes our proposal to make participation voluntary for all hospitals in approximately half of the geographic areas selected for participation in the Comprehensive Care for Joint Replacement (CJR) model (33 of 67 Metropolitan Statistical Areas [MSAs] selected; see 80 FR 73299 Table 4) and for low-volume and rural hospitals in all of the geographic areas selected for participation in the CJR model, beginning in performance year 3. It also implements several technical refinements and clarifications for certain CJR model payment, reconciliation, and quality provisions, and finalizes our proposed change to the criteria for the Affiliated Practitioner List to broaden the CJR Advanced Alternative Payment Model (Advanced APM) track.

As stated in the proposed rule, we note that reevaluation of policies and programs, as well as revised rulemaking, are within an agency's discretion, especially after a change in Administration. The EPMs and the CR Incentive Payment Model were designed and implemented as mandatory payment models via notice-and-comment rulemaking to test the effects of bundling cardiac and orthopedic care. The CJR model was also established as a mandatory payment model via notice-and-comment rulemaking to test the effects of bundling orthopedic episodes involving lower extremity joint replacements. The CJR model began on April 1, 2016 and is currently in its second performance year.

While we continue to believe that cardiac and orthopedic episode models offer opportunities to redesign care processes and improve quality and care coordination while lowering spending, we determined after careful review that it was necessary to propose to rescind the regulations at 42 CFR part 512, which relate to the EPMs and CR Incentive Payment Model, and reduce the scope of the CJR model for the following reasons. As stated in the proposed rule, we believe that requiring hospitals to participate in additional episode payment models at this time is not in the best interest of the Agency or the affected providers. Many providers are currently engaged in voluntary CMS initiatives, and we expect to continue offering initiatives, including episode-based payment models. Similarly, we also believe that reducing the number of providers required to participate in the CJR model will allow us to continue to evaluate its effects while limiting the geographic reach of our current mandatory models. As we mentioned in the proposed rule, we considered altering the design of the EPMs and the CR Incentive Payment Model to allow for voluntary participation and to take into account other feedback on the models. However, we noted that this would potentially involve restructuring the model design, payment methodologies, financial arrangement provisions, and/or quality measures, and we did not believe that such alterations would offer providers enough time to prepare, given the planned January 1, 2018 start date. In addition, if at a later date we test these or similar models, we would not expect to implement them through rulemaking if made voluntary but would employ the methods used to implement other voluntary models.

Finally, as stated in the proposed rule, we believe that cancelling the EPMs and CR Incentive Payment Model, as well as altering the scope of the CJR model, offers CMS flexibility to design and test other episode-based payment models while evaluating the ongoing CJR model. The CJR model has been operational for over a year and a half, and we have begun to provide participant hospitals initial financial and quality results from the first performance year. In many cases, CJR participant hospitals have invested in care redesign, and we want to recognize such commitments to improvement while reducing the number of hospitals that are required to participate.

We sought public comment on the proposals contained in the August 17, 2017 proposed rule (82 FR 39310 through 39333), and also on any alternatives considered.

2. Summary of Costs and Benefits

In the proposed rule, we stated that we did not anticipate that the cancellation of the EPMs and CR Incentive Payment Model prior to the start of those models would have any

costs to providers. As discussed in section II.A. of this final rule and interim final rule with comment period, some commenters noted that providers who assumed that the EPMs would begin on January 1, 2018, had incurred preparatory costs in terms of care pathway redesign and the creation of care coordinator positions. However, as the commenters did not specifically quantify these costs, we are unable to estimate them here. As shown in our impact analysis in section V. of this final rule and interim final rule with comment period, we estimate that the CJR model changes will reduce the previously projected CJR model savings (82 FR 603) by a total of approximately $108 million. Of the total projected reduction in savings, $106 million is attributable to CJR model changes over the final three performance years while approximately $2 million is attributable to the extreme and uncontrollable circumstance policy. Accordingly, we estimate that the total CJR model impact after the changes in this final rule will be $189 million, instead of $294 million ($106 million less in savings), over the remaining 3-year performance period (2018 through 2020) of the CJR model. Additionally, we estimate that the financial impacts resulting from the interim final rule with comment period will be a further reduction in savings of approximately $2 million during 2017, noting that we are implementing the extreme and uncontrollable circumstances policy (via an interim final rule with comment) in this rule for the 2017 reconciliation that will occur beginning in March of 2018. Our impact analysis has some degree of uncertainty and makes assumptions as discussed in section V. of this final rule and interim final rule with comment period. In addition to these estimated impacts, as with many of the Innovation Center models, the goals that participants are attempting to achieve include improving overall quality of care, enhancing participating provider infrastructure to support better care management, and reducing costs. We anticipate there will continue to be a broader focus on care coordination and quality improvement through the CJR model among hospitals and other providers and suppliers within the Medicare program that may lead to better care management and improved quality of care for beneficiaries.

3. Interim Final Rule Regarding Significant Hardship Due to Extreme and Uncontrollable Circumstances in the CJR Model

We are issuing this interim final rule with comment period in conjunction with this final rule in order to address the need for a policy to provide some flexibility in the determination of episode costs for CJR hospitals located in areas impacted by extreme and uncontrollable circumstances. Specifically, this policy would apply to CJR hospitals located in a county, parish, U.S. territory, or tribal government designated in a major disaster declaration under the Stafford Act, if as a result of the same major disaster the Secretary of Health and Human Services (the Secretary) authorized waivers under section 1135 of the Act.

B. Background

Under the authority of section 1115A of the Act, through notice-and-comment rulemaking, CMS' Center for Medicare and Medicaid Innovation (Innovation Center) established the CJR model in a final rule titled ''Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services'' published in the November 24, 2015 **Federal Register** (80 FR 73274 through 73554) (referred to in this final rule as the ''CJR model final rule''). We established three new models for acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes of care, which are collectively called the Episode Payment Models (EPMs), created a Cardiac Rehabilitation Incentive Payment Model (CR Incentive Payment Model), and revised several existing provisions for the CJR model, in a final rule titled ''Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model'' published in the January 3, 2017 **Federal Register** (82 FR 180) (referred to in this final rule as the ''EPM final rule'').

The effective date for most of the provisions of the EPM final rule was February 18, 2017, and in the EPM final rule we specified an effective date of July 1, 2017 for certain CJR model regulatory changes intended to align with a July 1, 2017 applicability, or start, date for the EPMs and CR Incentive Payment Model. On January 20, 2017, the Assistant to the President and Chief of Staff issued a memorandum titled ''Regulatory Freeze Pending Review'' that instructed Federal agencies to temporarily postpone the effective date for 60 days from the date of the memorandum for regulations that had been published in the **Federal Register** but had not taken effect, for purposes of reviewing the rules and considering potentially proposing further notice-and-comment rulemaking. Accordingly, on February 17, 2017, we issued a final rule in the **Federal Register** (82 FR 10961) to delay until March 21, 2017 the effective date of any provisions of the EPM final rule that were to become effective on February 18, 2017. We subsequently issued an interim final rule with comment (IFC) period in the **Federal Register** on March 21, 2017 (referred to in this final rule as the ''March 21, 2017 IFC'') (82 FR 14464). The March 21, 2017 IFC further delayed the effective date of the provisions that were to take effect March 21, 2017 until May 20, 2017, further delayed the applicability date of the EPMs and CR Incentive Payment Model provisions until October 1, 2017, and further delayed the effective date of the conforming CJR model changes until October 1, 2017. In the March 21, 2017 IFC, we also solicited public comment on further delaying the applicability date for the EPMs and CR Incentive Payment Model provisions, as well as the effective date for the conforming changes to the CJR model from October 1, 2017 until January 1, 2018 to allow for additional notice-and-comment rulemaking. Based on the public comments we received in response to the March 21, 2017 IFC, we published a final rule (referred to in this final rule as the ''May 19, 2017 final delay rule'') on May 19, 2017 (82 FR 22895) to finalize a January 1, 2018 applicability date for the EPMs and CR Incentive Payment Model provisions, as well as to finalize a January 1, 2018 effective date for the conforming changes to the CJR model (specifically amending § 510.2; adding § 510.110; amending § 510.120; amending § 510.405; amending § 510.410; revising § 510.500; revising § 510.505; adding § 510.506; and amending § 510.515). Additional changes to the CJR model, in accordance with the March 21, 2017 IFC, took effect May 20, 2017.

As we stated in the May 19, 2017 final delay rule (82 FR 22897), we received a number of comments on the models that did not relate to the start date change. These additional comments suggested that we reconsider or revise various model aspects, policies and design components; in particular, many of these comments suggested that we should make participation in the models voluntary instead of mandatory. We did not respond to these comments in the May 19, 2017 final delay rule, as the comments were out of scope of that rulemaking, but we stated that we might

take them into consideration in future rulemaking.

In the August 17, 2017 **Federal Register** (82 FR 39310 through 39333), we published a proposed rule that proposed to cancel the EPMs and CR Incentive Payment Model, and to rescind the regulations governing these models, as well as implement certain revisions to the CJR model.

We received approximately 85 timely pieces of correspondence containing multiple comments in response to the August 17, 2017 proposed rule. In the following sections of this final rule and interim final rule with comment period, we discuss our specific proposals, public comment, and our responses to those comments.

II. Provisions of the Proposed Regulations and Analysis of and Response to Public Comments

A. Cancellation of EPMs and Cardiac Rehabilitation Incentive Payment Model

In the January 3, 2017 EPM final rule, we established three bundled payment models for acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment (SHFFT) episodes, and a Cardiac Rehabilitation (CR) Incentive Payment Model. These models were similar to other Innovation Center models and focused on complex cases where we believe improvements in care coordination and other care redesign efforts offer the potential for improved patient outcomes and more efficient resource use. Many stakeholders, including commenters responding to the March 21, 2017 IFC, expressed concerns about provider burden and challenges these new models would present. We noted in the May 19, 2017 final delay rule (82 FR 22896), which finalized a January 1, 2018 start date for the EPMs and the CR Incentive Payment Model, that we would engage in notice-and-comment rulemaking on these models if warranted. We also noted that we received 47 submissions in response to the March 21, 2017 IFC. These responses contained a mix of in- and out-of-scope comments (82 FR 22899). In the May 19, 2017 final delay rule (82 FR 22897), we noted that in addition to commenting on the change to the effective date for the EPMs and CR Incentive Payment Model and certain provisions of the CJR model, commenters highlighted concerns with the models' design, including but not limited to: Participation requirements, data, pricing, quality measures, episode length, CR and skilled nursing facility (SNF) waivers, beneficiary exclusions and notification requirements, repayment, coding, and model overlap issues. Specifically, many commenters were opposed to the mandatory participation requirements, arguing that these models would force many providers who lack familiarity, experience, or proper infrastructure to quickly support care redesign efforts for a new bundled payment system. Many commenters were concerned that these mandatory models might harm patients and providers before CMS knows how these models might affect access to care, quality, or outcomes. Additionally, commenters were concerned that unrelated services would be incorporated into episode prices under the finalized price-setting methodology, in which we base prices on MS–DRGs and use clinical review to identify excluded, unrelated services rather than identifying included, related services. Commenters also expressed concern that this pricing approach would result in diagnosis codes classifying certain services as included, when in fact these services have no clinical relevance to the episode(s). Commenters were further concerned with the fact that CMS would progressively incorporate regional data into EPM target prices, where 100 percent of the EPM target price would be based on regional data by performance year 4. Commenters also took issue with the quality measures established for the SHFFT model, stating that these measures are not clinically related to the target population and are inappropriate for use in assessing the care provided to beneficiaries in the SHFFT model. In addition, commenters requested revisions to the CABG EPM to allow participants the option to use a CABG composite score developed by the Society of Thoracic Surgeons (STS) rather than the all-cause mortality measure.

Commenters also expressed concerns about the design of the CR Incentive Payment Model waivers. Commenters stated that current direct supervision requirements would continue to contribute to a lack of access to cardiac rehabilitation services and would inhibit providers' ability to redesign care for the CR Incentive Payment Model. Commenters suggested broadening the CR physician supervision waiver because the current waivers would not cover non-model beneficiaries who might be obtaining services concurrently with model participants and are therefore not sufficient. Other commenters were concerned with the precedence rules for model overlap with Models 2, 3 and 4 of the Innovation Center's Bundled Payments for Care Improvement (BPCI) initiative.

In the May 19, 2017 final delay rule (82 FR 22895), we stated that we might consider these public comments in future rulemaking. Based on our additional review and consideration of this stakeholder feedback, we concluded that certain aspects of the design of the EPMs and the CR Incentive Payment Model should be improved and more fully developed prior to the start of the models, and that moving forward with the implementation of the EPMs and CR Incentive Payment Model as put forth in the January 3, 2017 EPM final rule would not be in the best interest of beneficiaries or providers at this time. Based on our acknowledgment of the many concerns about the design of these models articulated by stakeholders, we proposed to cancel the EPMs and CR Incentive Payment Model before they began. Accordingly, we proposed to rescind 42 CFR part 512 in its entirety. We sought public comment on our proposal to cancel the EPMs and CR Incentive Payment Model.

We noted that, if the proposal to cancel the EPMs and CR Incentive Payment Model was finalized, providers interested in participating in bundled payment models would still have an opportunity to do so during calendar year (CY) 2018 via new bundled payment models. The Innovation Center expects to develop new bundled payment model(s) during CY 2018 that would be designed to meet the criteria to be an Advanced APM. We also noted the strong evidence base and other positive stakeholder feedback that we have received regarding the CR Incentive Payment Model. As we further develop the Innovation Center's portfolio of models, we may revisit this model and if we do, we will consider stakeholder feedback.

Comment: The majority of commenters supported cancellation of the EPMs, although many of these commenters noted that they support the general shift toward value-based payment models. Many of these commenters noted they supported deregulation in general and supported CMS' efforts to ease the administrative burden of mandatory models, voicing concern that mandatory models unduly burden hospitals who may be unprepared for model participation and compromise patient access and quality of care delivery. Other commenters stated that mandatory models disadvantage inexperienced or under-resourced providers, and are too complex. Commenters argued these providers, many of whom are smaller hospitals or systems, face logistical and

practical challenges that would be exacerbated by comparing all providers, and their varying levels of resources, to one another through a mandatory initiative. Commenters also argued that providers need models with greater flexibility, support, and incentives.

Several commenters supporting the cancellation of the EPMs stated that mandatory models fail to solicit and incorporate stakeholder feedback, and that CMS moved too quickly in finalizing the EPMs. Commenters stated that the models should be improved and more fully developed prior to the start of the models. Commenters highlighted concerns with many aspects of the models' design, including: Participation requirements; episode selection; data; pricing, especially the movement to regional pricing under the models; quality measures used in the models, especially for the CABG and SHFFT models; episode length; clinical homogeneity (or lack thereof) of the included patient population; episode inclusions and exclusions; CR and skilled nursing facility (SNF) waivers; beneficiary exclusions and notification requirements; reconciliation and repayment policies; and model overlap issues that impact providers already participating in APMs or other programs. Commenters also stated that there is insufficient evidence and evaluation of the efficacy of mandatory bundled payment models. They stated that the EPMs were not built upon the success of existing cardiac models, and that CMS should use this opportunity to gather broad stakeholder feedback.

Response: We thank commenters for their support for our proposal to cancel the EPMs. We agree with commenters' assertions that we should reduce provider burden when warranted, while maintaining the ability for providers to participate in future opportunities that shift towards value-based payment models. We continue to believe it is important to test and evaluate the effects of episode payment approaches on a broad range of Medicare providers. However, we agree with commenters that the design of the specific EPMs we are cancelling in this final rule and interim final rule with comment period should be further studied and refined, and we also agree with commenters that seeking additional stakeholder input in future model design is important. We note that in the recent Request for Information (posted on the CMS Web site at *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf*), CMS solicited comments through November 20, 2017 on suggestions for a new direction for the Innovation Center. CMS will carefully evaluate any input received regarding future models and the design of these models.

Comment: Several commenters contended that CMS lacks the authority to mandate participation in Innovation Center models. Commenters stated they do not believe that section 1115A of the Act provides CMS with the authority to mandate provider and supplier participation in Innovation Center models. These commenters stated that mandatory provider and supplier participation in models runs counter to both the letter and spirit of the law that established the Innovation Center, including the scope of its authority to test models under section 1115A of the Act and the directive to make recommendations to Congress set forth in section 1115A(g) of the Act. A commenter argued that the EPMs are a prohibited expansion in scope of the CJR model.

Response: We disagree that the Innovation Center lacks the authority to test mandatory models under section 1115A of the Act. Section 1115A of the Act authorizes the Secretary 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 (CHIP) beneficiaries. Section 1115A of the Act does not specify that participation in models must be voluntary. Moreover, the Secretary has 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 these Medicare payment and service delivery models. However, as we discuss later in this section, the Innovation Center will approach new model design with a focus on reducing provider burden. Finally, we disagree that the EPMs were an expansion of CJR. The SHFFT Model was designed as a separate and distinct model from the CJR model, utilizing different MS–DRGs.

Comment: Some commenters noted that the movement away from mandatory models represents a change in priorities from the previous administration. They acknowledged this change in preference from mandatory to voluntary model design but questioned that CMS continue to work toward achieving the goals of bundled payment models. They stated their desire to see CMS strike the best balance possible between reducing provider burden and incentivizing health system change that will allow for broad opportunities for Advanced APM participation beginning in CY 2018. A commenter noted that easing the regulatory burden on health systems and continuing the transition into value-based care need not be mutually exclusive goals.

Response: We agree with the commenter that easing regulatory burden on health systems and continuing the transition into value-based care are not mutually exclusive goals. As we noted in section I. of this final rule and interim final rule with comment period, review and reevaluation of policies and programs, as well as revised rulemaking, are within an agency's discretion, and that discretion is often exercised after a change in administration occurs. CMS is setting a new direction for the Innovation Center to promote patient-centered care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. We note that in the recent Request for Information (posted on the CMS Web site at *https://innovation.cms.gov/Files/x/newdirection-rfi.pdf*), CMS solicited comments through November 20, 2017 on suggestions for a new direction for the Innovation Center. As stated in the RFI, CMS believes that while existing partnerships with healthcare providers, clinicians, states, payers and stakeholders have generated important value and lessons, CMS is setting a new direction for the Innovation Center. New models will be designed to reduce burdensome requirements and unnecessary regulations to the extent possible to allow physicians and other providers to focus on providing high-quality healthcare to their patients. We appreciate the commenters' understanding of this change in priorities, and we reiterate CMS's commitment to developing models that reward value-based care and allow opportunities for Advanced APM participation for 2018 and future years.

Comment: Multiple commenters expressed concern that the cancellation of the EPMs will signal to the innovation community (that is, those who invest valuable resources into the development of new technologies and systems with the goal of transforming healthcare delivery) that healthcare payment policy is subject to the uncertainty of *ad hoc* reversal of transformative initiatives, thus stifling further innovation efforts. A commenter stated that cancellation of the EPMs will send signals that will slow the transformation of healthcare and confuse providers regarding the urgency

of system change from FFS to value-based payment. Another commenter stated that requiring providers to adapt to innovative, value-based payment models is preferable to reinforcing current, financially unsustainable payment models that incentivize the delivery of services without consideration for their cost, quality, and outcomes.

Response: We acknowledge the commenters' concerns about the signals that cancellation of the EPMs could send regarding our commitment to moving away from FFS toward value-based payment. We reiterate that CMS continues to explore new models to incentivize innovation and value-based payment and is committed to innovations that will foster an affordable, accessible healthcare system that puts patients first.

Comment: Many commenters objected to the outright cancellation of EPMs and stated that the models should be offered on a voluntary basis. These commenters expressed concern about the precedent established by the cancellation of a planned model after health systems have expended significant time and resources to prepare for participation in the initiative, and asserted that, without offering the option of voluntary participation, we would disadvantage health systems that had already made substantial investments in care redesign in anticipation of participating in EPMs, as this would not provide opportunity for return on those investments. Specifically, several commenters noted that since the finalization of the EPMs, providers have invested considerable time and funding in developing the necessary programs, processes, infrastructure and financial relationships in preparation for these programs. Commenters stated that while there may be limited or minimal additional costs required going forward with the cancellation of these models, it is worth nothing that significant investment was made by various stakeholders in preparation for them, particularly as they had been finalized by CMS. Multiple commenters stated that, since the finalization of the rule implementing EPMs, their health systems have already made significant investments and expended resources on care redesign to meet the payment models' requirements. While these commenters did not quantify the cost of these investments they noted that the investments included hiring care coordinators, re-engineering the process for admission from the Emergency Department for hip and femur fractures, and improving communication between their health system's regional hospitals and its main hospital, such that innovations in efficient and effective care coordination are already emerging from this implementation process. One commenter further stated that preparation for implementing the models resulted in a culture shift within their organization, especially with respect to communication and coordination between providers. Another commenter stated the time clinicians spent preparing for these models is ultimately a loss for patient care.

Response: We appreciate the commenters' support for voluntary versions of the EPMs. However, in reviewing the other comments received in support of the cancellation due to concerns with multiple aspects of the models, we continue to believe that there would not be enough time to sufficiently revise the models given the planned January 1, 2018 start date and that implementing these models as originally designed would not be in the best interest of beneficiaries or providers. We thank the commenters for their submissions noting that providers have invested in infrastructure, increased staffing, and care redesign in response to the mandatory nature of the EPMs. We appreciate these initiatives taken by hospitals selected for the EPMs and thank them for bringing these actions to our attention. We note that commenters did not provide enough detail about the hiring status or educational and licensing requirements of any care coordinator positions they may have created and filled (that is, full or part-time, Registered Nurse or non-Registered Nurse, scope of work, etc.) for us to quantify an economic impact for these case coordination investments. Likewise investments in re-engineering of processes and communication systems were not quantified and thus preclude us from attempting to estimate a dollar value impact. We believe that these investments and preparations will position providers for successful participation in future initiatives that may provide opportunities for return on these investments. Further we believe hospitals that made preparations, especially those that have created new care coordinator positions that they intend to keep staffed and those that have implemented process improvements that they intend to keep in place, are likely to provide enhanced patient care by improving the efficiency and quality of care for Medicare beneficiaries and improving the coordination of care from the initial hospitalization through recovery, rather than reverting to previous practices that may not have placed as much emphasis on efficiency, quality, and care coordination. As we remain committed to moving toward value-based payment, we believe that investments in care coordination and quality improvement will ultimately benefit both providers and patients.

Comment: Some commenters stated their opposition to the cancellation of EPM models and stated that they should be implemented as mandatory models. A commenter stated the belief that providers would have adapted to the models and beneficiaries' access to care would not have been affected, and suggested that, rather than cancelling the models, CMS should further delay the start date to allow providers more time to prepare for implementation of the models. Other commenters noted that mandatory models, compared to voluntary models, create a more reliable experiment with the ability to generate evidence of bundled payments' effectiveness, and they increase the chances of bringing bundled payments to scale nationally. Another commenter stated that they support mandatory models because they are necessary to eliminate the ''pilot program'' mentality of providers. A commenter noted that voluntary models provide opportunities for gaming. Another commenter asserted that the rationale used by CMS to rescind the EPMs is flawed and contradicts statements outlined in the EPM final rule. This commenter further stated that, while there will always be innovators who will participate in voluntary models and guide their peers in systematic improvements leading to changes in overall healthcare delivery, non-participant providers have been reluctant to accept a change in their clinical practice and as a result have not demonstrated the clinical improvement that others have seen, due to the lack of a mandate for change. This commenter expressed concern that without mandatory models, improvement will not remain consistent and there will likely be a reversion to ''the norm.'' Another commenter stated their opposition to the cancellation of EPMs and their belief that mandatory models should be implemented more broadly. This commenter further stated their belief that the cancellation of EPMs represents an attempt to delay the move to value-based reimbursement and maintain the FFS reimbursement model, which will benefit the financial interests of healthcare companies at the expense of the well-being and economic interests of the healthcare consumer and American taxpayer. Another commenter similarly stated their opposition to the

cancellation of EPMs based on their concern about the long term fiscal solvency of Medicare.

Response: We appreciate the commenters pointing out some of the specific benefits of mandatory, as opposed to voluntary, models. We agree generally that mandatory models have certain advantages over voluntary models, and we have had to weigh those advantages against our goals of minimizing provider burden at this time and against the design-related concerns raised by stakeholders for these specific EPM and CR Incentive Payment Models. Furthermore, although we monitor provider behavior to be sure that hospitals' implementation strategies are in compliance with the CJR model and other Medicare requirements, and to identify individual providers that merit additional investigation, educational outreach, or referral to program integrity contractors, cancelling the EPMs will provide more time to fully evaluate the impact of CJR.

However, we take seriously the commenters' concerns about the urgency of continuing our movement toward value-based care in order to accommodate an aging population with increasing levels of chronic conditions, while also acting as responsible stewards of the Medicare Trust Funds. We continue to believe that value-based payment methodologies will play an essential role in lowering costs and improving quality of care, which will be necessary in order to maintain Medicare's fiscal solvency. At this time, we believe that focusing on the development of different bundled payment models and engaging more providers in these models is the best way to drive health system change while minimizing provider burden and maintaining patient access to care.

Comment: We received many comments in support of our proposal to cancel the CR Incentive Payment model. Commenters supporting our proposal to cancel the CR Incentive Payment Model lauded the decelerated implementation of mandatory models and noted that the mandatory CR Incentive Payment Model would have created additional undue administrative burden for providers. Many of these commenters suggested that the CR Incentive Payment Model would strain hospitals' limited resources, leading to decreased access to care or quality of care.

Response: We appreciate some commenters' support of our proposal to cancel the mandatory CR Incentive Payment Model. We agree with the commenters that it is important to lessen provider burden where we can.

Comment: Several commenters opposed CMS' proposal to cancel the CR Incentive Payment Model. These commenters stated that they saw the CR Incentive Payment Model as an important step toward value-based payments and that cancelling the CR Incentive Payment Model would result in a missed opportunity to collect evidence. Commenters opposing the cancellations also cited the financial investments providers made in preparation for the model. Some of these commenters felt that a mandatory cardiac model would force otherwise-hesitant providers to focus on enhanced care management, improved infrastructure, and cost reduction. Several commenters cited evidence of the effectiveness of cardiac rehabilitation and its relatively low utilization levels as support for continuing the model, stating that it would be an effective test with or without concurrent EPM implementation. A commenter stated that implementing the CR Incentive Payment Model alone would provide independent testing of its effects, and some commenters requested that the model continue as a limited pilot.

Response: We thank commenters for their input and note that we agree with the premise cited by commenters that the CR Incentive Payment Model could provide an opportunity to collect evidence and may support provision of an under-utilized yet effective intervention. However, we believe that the nature of the CR Incentive Payment Model does not permit sufficient provider choice and our intention in removing this mandatory model at this time is to enhance providers' ability to determine the models and initiatives that suit their organizations while increasing quality and value-based payments. Additionally, we note the obstacles presented by the cancellation of the cardiac EPMs and conforming regulations with which this model is aligned. Due to the manner in which the regulations guiding the cardiac EPMs were interwoven with those of the CR Incentive Payment Model, we do not believe it would be feasible to continue the mandatory CR Incentive Payment Model alone at this time since we are cancelling the EPMs and rescinding all of the associated regulations. However, as we stated in the proposed rule, as we further develop the Innovation Center's portfolio of models, we may revisit the concept of a model with a focus on cardiac rehabilitation and, if we do, will consider stakeholder feedback.

Comment: Many commenters stated that the CR Incentive Payment Model required improvements prior to implementation, including many who requested that it continue as a voluntary model. A few requested that we solicit more stakeholder feedback throughout model development, while others requested altered or new model waivers. Many commenters supporting cancellation of the CR Incentive Payment Model recommended that any potential future iterations of the model should be separate from other APMs. A commenter asserted that the CR Incentive Payment Model could be effective without incentivizing such a high number of CR or intensive cardiac rehabilitation (ICR) services. Another commenter recommended allowing shared financial arrangements among CR programs.

Response: We thank commenters for suggested improvements to the CR Incentive Payment Model, and would consider this input for any future cardiac rehabilitation models.

Comment: Many commenters encouraged CMS to expedite the introduction of the new voluntary bundled payment models that would meet the criteria to be Advanced APMs. Commenters noted making new voluntary models available as soon as possible will allow hospitals to capitalize on the preparations they made in anticipation of the EPMs and will also allow them to partner with clinicians to provide better quality, more efficient care. Commenters are concerned that the ambiguity surrounding the future of EPMs has posed challenges for hospitals attempting to determine where and how to invest in implementation. Commenters supported the development of new models that meet the Advanced APM definition under the Quality Payment Program and urged CMS to build upon the lessons learned in the Bundled Payments for Care Improvement (BPCI) initiative. A commenter urged CMS to align advancements included in the CJR and EPM models into a new bundled payment model. A commenter recommended that CMS ensure that a voluntary model is available when the current BPCI initiative expires. Several commenters urged CMS to implement new voluntary models before the proposed voluntary election period for CJR (January 1–January 31, 2018) to give these providers as well as BPCI participants adequate time to prepare for future models. Commenters suggested that in the alternative, CMS should implement new voluntary models prior to BPCI's conclusion in September 2018. A commenter urged CMS to limit the size and scope of future models and ensure open and

transparent communication with stakeholders during model development. Commenters suggested that CMS should release data on baselines and targets in advance of a model's application deadline to allow entities to prepare for the most appropriate models. Commenters encouraged CMS to initiate collaborative process between CMS, providers and other stakeholders as they stated this would result in more robust and effective models.

Response: We note providers' interest in future bundled payment models that meet the criteria to be an Advanced APM and are considering options for developing such models.

Comment: Numerous commenters suggested changes to the overall design of the EPMs, CR Incentive Payment Model, BPCI initiative, and CJR model that were outside of the scope of the August 17, 2017 proposed rule. These comments touched on model participation requirements, data, pricing, choice of quality measures used, episode length, CR and SNF waivers, beneficiary exclusions and notification requirements, repayment, coding, model overlap issues, and the inclusion of depression screening in models. Additionally we received public comments suggesting alternative model proposals that include physician-based, outcome-based, procedure-based, specialty-based, and Medicare Advantage APMs. Commenters recommended that the CJR model and future models provide more collaboration opportunities and offer broader waivers of fraud and abuse laws, such as the physician self-referral law commonly known as the ''Stark Law,'' and the Anti-Kickback statute. Several commenters stated that the ''Stark Law,'' which they contend has not been updated statutorily for over 2 decades, is challenging to work through when developing financial arrangements, as small, unintentional technical errors on the part of physicians or staff could lead to heavy penalties under this strict liability statute, and that the cost of compliance and disclosure can be prohibitive to small and medium practices who would otherwise want to participate in new models. Commenters encouraged data transparency and access to substance abuse claims, an APM Ombudsman, differing episode durations, a uniform model overlap policy, use of care coordinators, pricing and reconciliation modifications, different quality measures, and clarification of certified electronic health record technology (CEHRT) requirements.

Response: We consider these public comments to be outside of the scope of the August 17, 2017 proposed rule; and therefore, we are not addressing them in this final rule and interim final rule with comment period. We may consider these public comments in future rulemaking.

Summary of Final Decisions: We are finalizing our proposal to cancel the Episode Payment Models (EPMs) and Cardiac Rehabilitation (CR) Incentive Payment Model and to rescind the regulations at 42 CFR part 512.

B. Changes to the CJR Model Participation Requirements

1. Voluntary Participation Election (Opt-In) for Certain MSAs and Low-Volume and Rural Hospitals

The CJR model began on April 1, 2016. The model is currently nearing completion of the second performance year, which includes episodes ending on or after January 1, 2017 and on or before December 31, 2017. The third performance year, which includes all CJR episodes ending on or after January 1, 2018 and on or before December 31, 2018, would necessarily incorporate episodes beginning before January 2018. The fifth performance year will end on December 31, 2020. Currently, with limited exceptions, hospitals located in the 67 geographic areas selected for participation in the CJR model must participate in the model through December 31, 2020; that is, their participation in the CJR model is mandatory unless the hospital is an episode initiator for a lower-extremity joint replacement (LEJR) episode in the risk-bearing period of Models 2 or 4 of the BPCI initiative. Hospitals with a CCN primary address in one of the 67 selected geographic areas selected for CJR that participated in Model 1 of the BPCI initiative, which ended on December 31, 2016, began participating in the CJR model when their participation in the BPCI initiative ended.

Based on smaller, voluntary tests of episode-based payment models and demonstrations, such as the Acute Care Episode (ACE) demonstration and the BPCI initiative, that have indicated a potential to improve beneficiaries' care while reducing costs (see ACE evaluation at: *https://downloads.cms.gov/files/cmmi/ace-evaluationreport-final-5-2-14.pdf* and BPCI evaluation at: *https://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf*), we finalized the CJR model with mandatory participation in the 67 selected geographic areas so that we could further test delivery of better care at a lower cost across a wide range of hospitals, including some hospitals that might not otherwise participate, in many locations across the country. In the CJR model final rule (80 FR 73276), we stated that we believed that by requiring the participation of a large number of hospitals with diverse characteristics, the CJR model would result in a robust data set for evaluation of this bundled payment approach, and would stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner would also allow us to learn more about patterns of inefficient utilization of healthcare services and how to incentivize the improvement of quality for common LEJR procedure episodes.

After further consideration of stakeholder feedback, including responses we received on the March 21, 2017 IFC, we proposed certain revisions to the mandatory participation requirements for the CJR model to allow us to continue to evaluate the effects of the model while limiting the geographic reach of our current mandatory models. Specifically, we proposed that the CJR model would continue on a mandatory basis in approximately half of the selected geographic areas (that is, 34 of the 67 selected geographic areas), with an exception for low-volume and rural hospitals, and continue on a voluntary basis in the other areas (that is, 33 of the 67 selected geographic areas).

The geographic areas for the CJR model are certain Metropolitan Statistical Areas (MSAs) that were selected following the requirements in § 510.105 as discussed in the CJR model final rule (80 FR 73297 through 73299). In § 510.2, an MSA is defined as a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000. In selecting the 67 MSAs for inclusion in the CJR model, the 196 eligible MSAs were stratified into 8 groups based on MSA average wage adjusted historic LEJR episode payments and MSA population size (80 FR 41207). Specifically, we classified MSAs according to their average LEJR episode payment into four categories based 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 CJR model proposed rule (80 FR 41198). This approach ranked the MSAs relative to one another and created four equally sized groups of 49. The population distribution was divided at the median point for the MSAs eligible for potential selection, creating 8 groups. Of the 196 eligible MSAs, we chose 67 MSAs via a stratified random selection process as

discussed in the CJR model final rule (80 FR 73291).

In reviewing our discussion of the MSA selection and the MSA volume needed to provide adequate statistical power to evaluate the impact of the model in the CJR model final rule (80 FR 73297), we determined that reducing the mandatory MSA volume in half by selecting the 34 MSAs with the highest average wage-adjusted historic LEJR episode payments for continued mandatory participation could allow us to evaluate the effects of the CJR model across a wide range of providers, including some that might not otherwise participate in the model. Higher payment areas are most likely to have significant room for improvement in creating efficiencies and greater variations in practice patterns. Thus, the selection of more expensive MSAs was the most appropriate approach to fulfilling the overall priorities of the CJR model to increase efficiencies and savings for LEJR episodes while maintaining or improving the overall quality of care.

The original determination of the sample size need in the CJR model final rule was constructed to be able to observe a 2-percent reduction in wage-adjusted episode spending after 1 year. This amount was chosen based on the anticipated amount of the discount applied in the target price. In considering the degree of certainty that would be needed to generate reliable statistical estimates, we assumed a 20-percent chance of false positive and a 30-percent chance of a false negative. Using these parameters, we determined that the number of MSAs needed ranged from 50 to 150. In order to allow for some degree of flexibility, we selected 75 MSAs, which were narrowed to 67 due to final exclusion criteria.

As we reviewed the CJR model for the August 17, 2017 proposed rule, we noted that, excluding quarterly reconciliation amounts, evaluation results from BPCI Model 2 indicated possible reductions in fee-for-service spending of approximately 3 percent on orthopedic surgery episodes for hospitals participating in the LEJR episode bundle (*https://innovation.cms.gov/Files/reports/bpci-models2-4-yr2evalrpt.pdf*). We examined the sample size needed to detect a 3-percent reduction in CJR model episode spending after 1 year using the same methodology as described in the CJR model final rule. We determined that we would be able to meet this standard with 34 MSAs from the higher cost groups. We noted that we expect that hospitals in the higher cost MSAs will be able to achieve similar 3-percent savings given their MSA's relatively high historic episode spending and thus greater opportunities for improvements, and their experience over the first 2 performance years of the CJR model. We noted that the proposed changes to the model, including the focus on higher cost MSAs and the reduced number of mandatory MSAs, would cause changes to the nature of the evaluation.

To select the 34 MSAs that would continue to have mandatory participation (except for low-volume and rural hospitals), we took the distribution of average wage-adjusted historic LEJR episode payments for the 67 MSAs using the definition described in the CJR model final rule, ordered them sequentially by average wage-adjusted historic LEJR episode payments, and then selected the 34 MSAs with the highest average payments. We noted that under the proposal to reduce the number of MSAs with mandatory participation, the remaining 33 MSAs would no longer be subject to the CJR model's mandatory participation requirements; that is, hospital participation would be voluntary in these 33 MSAs.

After dividing the 67 MSAs into 34 mandatory and 33 voluntary MSAs as described previously, we examined selected MSA characteristics. In order to determine whether a good balance was maintained across MSA population size, we examined the number of MSAs below and above the median population point of the 196 MSAs eligible for potential selection. We observed that a good balance of MSA population size was maintained (17 out of 34 mandatory and 17 out of 33 voluntary MSAs had a population above the median population). While the 34 MSAs that would continue to have mandatory participation have higher spending on average, these MSAs all include providers with average cost episodes in addition to providers with high cost episodes. In general, we noted that hospitals located in higher cost areas have a greater potential to demonstrate significant decreases in episode spending. However, within the higher cost MSAs, there was still significant variation in characteristics and experiences of the included hospitals. We anticipated that the evaluation would be able to assess the generalizability of the findings of the CJR model by examining variations of performance within the participating hospitals that represent a wide range of hospital and market characteristics. Therefore, we proposed that the CJR model would have 34 mandatory participation MSAs (identified in Table 1) and 33 voluntary participation MSAs (identified in Table 2) for performance years 3, 4, and 5.

Specifically, we proposed that, unless an exclusion in § 510.100(b) applies (that is, for certain hospitals that participate in the BPCI initiative), participant hospitals in the proposed 34 mandatory participation MSAs that are not low-volume or rural (as defined in § 510.2 and discussed in the following paragraphs) would continue to be required to participate in the CJR model. We also proposed that hospitals in the proposed 33 voluntary participation MSAs and hospitals that are low-volume or rural (as defined in § 510.2 and discussed in the following paragraphs) would have a one-time opportunity to notify CMS, in the form and manner specified by CMS, of their election to continue their participation in the CJR model on a voluntary basis (opt-in) for performance years 3, 4, and 5. We noted that hospitals that choose to participate in the CJR model and make a participation election that complies with proposed § 510.115 would be subject to all model requirements. Hospitals in the proposed 33 voluntary participation MSAs and low-volume and rural hospitals (as defined in § 510.2 and discussed in the following paragraphs) that do not make a participation election would be withdrawn from the CJR model as described later in this section of this final rule and interim final rule with comment period.

We proposed to exclude and automatically withdraw low-volume hospitals in the proposed 34 mandatory participation MSAs, as identified by CMS (see Table 3), from participation in the CJR model effective February 1, 2018. Since some low-volume hospitals may want to continue their participation in the CJR model, we proposed to allow low-volume hospitals to make a one-time, voluntary participation election that complies with the proposed § 510.115 in order for the low-volume hospital to continue its participation in the CJR model. We proposed to define a low-volume hospital in § 510.2 as a hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the performance year 1 CJR episode target prices. Note that under this definition, all hospitals listed in Table 3 would meet the definition of a low-volume hospital, but this list would not be inclusive of all hospitals that could be identified by CMS as a low-volume hospital. For example, a new hospital (with a new CCN) that opens in a mandatory MSA during the remaining years of the CJR model would not have

any LEJR episodes during the historical years of data used to calculate the performance year 1 CJR episode target prices. Under our proposal, we intended that any hospital with a new CCN that came into existence after the proposed voluntary participation election period would not be required or eligible to join the CJR model. We noted that our proposed policy for new hospitals would not be applicable in the case of a reorganization event where the remaining entity is a hospital with a CCN that was participating in the CJR model prior to the reorganization event; consistent with our current policy, such hospital would continue participation in the CJR model regardless of whether all predecessor hospitals were participant hospitals prior to the reorganization event.

We also proposed to exclude and automatically withdraw rural hospitals from participation in the CJR model effective February 1, 2018. Since some rural hospitals may want to continue their participation in the CJR model, we proposed to allow rural hospitals to make a one-time, voluntary participation election that complies with the proposed § 510.115 in order for the rural hospital to continue its participation in the CJR model. Specifically, we proposed that rural hospitals (as defined in § 510.2) with a CCN primary address in the 34 mandatory participation MSAs would have a one-time opportunity to opt-in to continue participation in the CJR model during the proposed voluntary participation election period. We proposed that a hospital's change in rural status after the end of the voluntary participation election period would not change the hospital's CJR model participation requirements. Specifically, we proposed that hospitals in the proposed 34 mandatory participation MSAs that are neither low-volume or rural hospitals during the proposed voluntary participation election period would be required to participate in the CJR model for performance years 3, 4, and 5, and that these hospitals would continue to be required to participate in the CJR model even if they subsequently become a rural hospital. Similarly, we proposed that a rural hospital that makes a voluntary participation election during the one-time opportunity would be required to continue participating in the CJR model if that hospital no longer meets the definition of rural hospital in § 510.2. We proposed this approach so that CMS could identify the hospitals, by CCN, that would participate in the model for the remainder of performance year 3 and performance years 4 and 5 at the conclusion of the proposed voluntary participation election period and so that there would be less confusion about which hospitals are CJR model participants.

We also stated that we believe that our proposed approach to make the CJR model primarily concentrated in the higher cost MSAs where the opportunity for further efficiencies and care redesign may be more likely and to allow voluntary participation in the lower cost MSAs and for low-volume and rural hospitals allows the Innovation Center to focus on areas where the opportunity for further efficiencies and care redesign may be more likely, while still allowing hospitals in the voluntary MSAs the opportunity to participate in the model. In developing the proposed rule, we considered that hospitals in the CJR model had been participating for over a year and a half as of the timing of the proposed rule, and noted that we had begun to give hospitals in the model initial financial and quality results from the first performance year. In many cases, participant hospitals had made investments in care redesign, and we wanted to recognize such investments and commitments to improvement while reducing the overall number of hospitals that are required to participate. We also considered stakeholder feedback that suggested we make participation in the CJR model voluntary, and the model size necessary to detect at least a 3-percent reduction in LEJR episode spending. Taking these considerations into account, we considered whether revising the model to allow for voluntary participation in all, some, or none of the 67 selected MSAs would be feasible.

As discussed in section V. of this final rule and interim final rule with comment period (see 82 FR 39327 through 39331 for proposed rule impact estimates), the estimated impact of the changes to the CJR model we are finalizing in this final rule and interim final rule with comment period are estimated to reduce the overall estimated savings for performance years 3, 4, and 5 by $106 million. An additional estimated $2 million in reduced savings is estimated for the performance year 2 reconciliation that will occur in March of 2018 and will incorporate the extreme and uncontrollable circumstances policy we are putting into place in with the interim final rule with comment in this rule for a total reduction in the originally projected CJR model savings of $108 million. If voluntary participation was allowed in all of the 67 selected MSAs, the overall estimated model impact would no longer show savings, and would likely result in additional costs to the Medicare program. If participation was limited to the proposed 34 mandatory participation MSAs and voluntary participation was not allowed in any MSA, the impact to the overall estimated model savings over the last 3 years of the model (excluding the impact of the extreme and uncontrollable circumstances policy in the interim final rule with comment period portion of this rule) would be closer to a reduction of $45 million than the reduction of $106 million estimate presented in section V. of this final rule, because our modeling, which does not include assumptions about behavioral changes that might lower fee-for-service spending, estimates that 60 to 80 hospitals will choose voluntary participation. Since we estimated that these potential voluntary participants would be expected to earn only positive reconciliation payments under the model, these positive reconciliation payments would offset some of the savings garnered from mandatory participants. However, as many current hospital participants in all of the 67 MSAs are actively invested in the CJR model, we proposed to allow voluntary participation in the 33 MSAs that were not selected for mandatory participation and for low-volume and rural hospitals.

We sought comment on this proposal.

Comment: Several commenters disagreed with our proposal to make CJR voluntary in certain MSAs. Commenters noted that in some cases, they believe their hospitals have reduced spending and improved quality of care as well as patient satisfaction as a result of mandated participation in CJR. A commenter stated that due to mandated participation in CJR, it is now more likely they will elect to participate in other voluntary initiatives in the future. Other commenters stated that the current model of mandatory participation in all 67 MSAs allows for more generalizable evaluation results, and that allowing for voluntary participation in half of the current MSAs will negatively impact the evaluation. Some believe the proposal to offer hospitals in approximately half of the geographic areas the option to opt-in to the model on a voluntary basis will incentivize patient selection (that is, select only healthier patients for LEJR procedures) and limit CMS' ability to improve beneficiary health and the financial viability of the Medicare program. Several commenters stated that the proposal would stifle innovation, resulting in providers

hesitating before engaging in further innovative payment efforts and incentivizing only high-performing hospitals to continue participation in the voluntary MSAs. A commenter wrote that they believe it is too early to limit the scope of the CJR model and that doing so will halt our ability to produce data on the impact of the model on quality and cost.

Response: We thank commenters for their responses. We continue to believe that by limiting the geographic areas in which CJR is mandatory at this time, we are encouraging innovation by reducing burden on providers to participate in models. We also believe that our proposal will not incentivize patient selection, as we will continue to monitor hospitals in CJR for changes in patient case-mix, and we are only allowing for a one-time opt-in for eligible hospitals. Hospitals that opt-in to the model, as discussed later in this section, will remain in CJR for the remaining 3 performance years and will not have the opportunity to later opt-out. In addition, all other current requirements of participation, such as notifying beneficiaries about the model, remain in place. We also note that we expect the CJR model to produce savings for the Medicare program, as detailed in section V. of this final rule, and to improve the quality of care provided to beneficiaries undergoing LEJR procedures. Providers in voluntary MSAs who have made investments and want to continue participating in CJR may do so by opting into the model. We also reiterate that we are considering options for a new bundled payment initiative, as discussed previously in section II.A. of this final rule, which could provide additional participation opportunities for providers currently in CJR, including low volume and rural providers, as well as hospitals located in voluntary MSAs, that choose not to opt-in to CJR. Finally, we believe that we will still be able to evaluate the CJR model, given these policy changes. After examining the remaining 34 mandatory MSAs, we observed that there remains significant variation in the types of markets and hospitals who will continue participation in the model across a broad representation of geographic regions. This wide variation in hospital and market characteristics will allow us to evaluate variations in impact and assess the generalizability of the findings of the CJR model. Additionally, the anticipated inclusion of hospitals in the voluntary MSAs who opt-in has a high likelihood of resulting in a robust data set for the evaluation of generalizability of findings in mandatory areas that moved to voluntary participation.

Comment: Many commenters supported our proposal to make CJR voluntary in 33 MSAs and voluntary for all rural and low volume providers in CJR. However, several commenters requested we make CJR voluntary in all 67 MSAs, effectively removing any mandatory participation. Commenters opposed mandatory participation in payment models due to providers' differing levels of experience with risk and infrastructure capabilities and because some providers may not be well-positioned to take on financial risk for a specific patient population. Several commenters cited concerns with beneficiary access and the quality of patient care under mandatory initiatives. A commenter stated that mandatory models penalize providers that have not already participated in other voluntary initiatives like BPCI. Other commenters opposed mandatory models due to a belief that quality of care is more likely to improve when health providers actively choose to participate in payment models. Several commenters stated that under our proposal, physicians and other teams of providers in voluntary MSAs could still utilize the flexibility and resources under CJR to improve patient care and would be incentivized to do so.

Other commenters requested that CMS make the model voluntary in all MSAs across the country, not just those 67 currently participating in CJR, in order to increase participation opportunities in Advanced APMs and to treat hospitals in all 67 current CJR MSAs fairly by not mandating participation in some areas and not others. Several commenters noted support for our proposal to make CJR voluntary in certain areas, but requested that CMS clarify that our priorities still include delivery system reform given that our proposal would limit the reach of an existing model.

Response: We thank those commenters that supported the proposal. We note that although we are reducing the number of MSAs where participation in the CJR model is mandatory, we continue to believe that the CJR model offers opportunities for providers to improve the quality of care while reducing spending. We expect many providers in the voluntary MSAs to elect to continue participation in the CJR model, and look forward to continuing to work with all CJR participant hospitals to improve quality of care under the model. Delivery system reform and movement toward value-based payment remain CMS priorities; we believe offering more opportunities for providers to engage in such activities on a voluntary basis will allow us to continue to pursue our goals.

We continue to believe that offering voluntary participation in 33 MSAs while maintaining mandatory participation in the remaining 34 MSAs is the correct path forward at this time. As discussed previously, we will continue to require hospitals in the 34 highest-cost MSAs to participate in CJR because we believe that those geographic areas have significant opportunity for reducing episode spending while improving quality of care under the model. Similarly, we believe that at this point in the CJR model (the end of the second performance year), it is most prudent for us to continue the model in the geographic areas where providers have already implemented infrastructure changes as well as received initial financial and quality results for the first performance year. In addition, as discussed previously, participation will remain mandatory in the 34 higher-cost MSAs where we believe there exists significant opportunity to reduce episode spending. In lieu of increasing the number of MSAs participating in CJR at this time, we are focusing our efforts on development of other new models that will further address our goals of improving quality of care and reducing spending.

Comment: Several commenters supported our proposal to make participation in CJR voluntary in some of the current MSAs but objected to our use of the high-cost criterion to determine which MSAs should remain mandatory. These commenters requested that we randomly select which MSAs would remain mandatory or include a mixture of high- and low-cost MSAs in the remaining mandatory areas.

Response: We thank the commenters for their suggestions but continue to believe that choosing the higher-cost MSAs for mandatory participation is appropriate, especially given the transition to fully regional pricing in performance years 4 and 5 of the CJR model. The higher-cost MSAs may offer more opportunity for hospitals in CJR to reduce episode spending and improve quality, especially as target prices move to fully regional prices in year 4 of the model.

Comment: A number of commenters supported our proposal to allow low volume hospitals in all 67 MSAs to participate in the model on a voluntary basis, but requested that we revise the low volume threshold to offer voluntary participation to a larger number of

hospitals. Commenters specifically requested we revise the threshold to 100 episodes across the 3-year historical baseline (episodes that began in 2012–2014), noting their belief that hospitals with fewer episodes have experienced more pricing volatility and have a more difficult time managing care redesign and episode spending under bundled payment models.

Response: We proposed to define low volume hospitals as those hospitals with fewer than 20 episodes in the 3-year historical baseline period (episodes in 2012 through 2014) used to create PY1 episode target prices. We note that this definition is consistent with our treatment of low volume hospitals currently participating in CJR; since the model's inception, under § 510.300(b)(3), such hospitals receive a 100 percent regional target price in all years of the model. This threshold represents approximately the 10th percentile of episode volume across hospitals, which we believed was a reasonable threshold. In addition, such hospitals are defined as low volume for purposes of the CJR model based only on their historical LEJR episode volume among Medicare FFS beneficiaries; while these hospitals may furnish few LEJR procedures to Medicare FFS beneficiaries, they are not necessarily rural or low volume in terms of bed count or the volume of other services provided. In response to commenters' suggestion to revise the threshold, we reexamined our data on episode volume across the historical baseline, as well as the initial performance year 1 reconciliation results.

We are finalizing our proposal to define low volume hospitals as those with fewer than 20 episodes in the historical baseline period for the following reasons. First, we note that a number of low volume hospitals earned initial reconciliation payments for performance year 1, indicating that having a low volume of episodes among Medicare FFS beneficiaries does not preclude a hospital from achieving care redesign and financial success under the model. Second, we are attempting to balance competing considerations, including not wanting to overburden smaller providers, while still learning how these types of providers perform in an episode model like CJR. We will continue to operate CJR as a mandatory model in 34 MSAs so that we may better understand how providers who typically do not participate in voluntary models respond to an episode payment structure. In addition, small hospitals are currently underrepresented in voluntary Innovation Center models. Thus, we are particularly interested in learning about their experiences as participants so that, when we examine whether the statutory requirements for expansion are met for CJR, we can consider these experiences rather than assuming that the experience of larger hospitals can be simply applied to them. We believe that the current manner of defining low volume hospitals as those having fewer than 20 episodes strikes an appropriate balance between wanting to understand the experience of hospitals with different care patterns and populations while limiting unnecessary burden.

Comment: Commenters supported our proposal to make participation voluntary for rural hospitals in all 67 CJR MSAs. Commenters noted that our proposal to allow for voluntary participation in CJR for all rural hospitals recognizes the unique challenges that rural hospitals face, including more limited access to infrastructure.

Response: We thank the commenters for their support. We agree that rural hospitals face unique challenges related to caring for their patient populations and are finalizing our policy to allow rural hospitals in all 67 CJR MSAs to opt-in to continue participation in the model.

Comment: Several commenters requested that CMS clarify how the CJR regional target prices will change if the proposal is finalized.

Response: We are clarifying that regional targets will not change because they incorporate all lower-extremity joint replacement episodes in a U.S. Census Division, regardless of MSA and CJR participation.

Comment: A commenter requested clarification on the proposed CJR participation requirements for hospitals currently participating in BPCI for LEJR episodes. The commenter noted that under our proposed policy, it was unclear whether a hospital participating in BPCI for LEJR episodes would enter CJR upon terminating participation on BPCI, or when the current BPCI initiative ends in September 2018. The commenter believes that requiring hospitals to enter CJR starting in the fourth performance year could expose them to undue financial risk, given that CJR will transition to fully regional pricing for performance years 4 and 5 of the model.

Response: We note that we did not propose any changes to the CJR participation requirements with relation to BPCI precedence. Hospitals that are participating in the BPCI initiative for LEJR episodes are not required to participate in CJR. We did not propose a special election period for BPCI hospitals that terminate from BPCI (or stop participating in LEJR episodes under that initiative). In other words, a hospital that terminates from BPCI after January 1, 2018 and that is located in a voluntary area or that qualified as a rural or low volume provider under the CJR definitions as of January 31, 2018 would not be required or able to participate in CJR. When BPCI concludes its final performance period, we will not offer a special election period. At that time, hospitals in mandatory CJR MSAs who do not qualify as rural or low volume under the CJR definitions must participate in CJR, as specified in § 510.100(b). Our expectation is that hospitals that have been participating in BPCI will have a smooth transition into CJR based on their experience in managing episodes under the BPCI model. Hospitals not in mandatory areas or hospitals that have rural or low volume status under the CJR definitions interested in participating in voluntary bundled payment models would have other opportunities to apply to do so, as discussed in section II.A. of this final rule and interim final rule with comment period.

TABLE 1—CJR MANDATORY PARTICIPATION MSAS

MSA	MSA name	Wage-adjusted episode payments (in $)
10420	Akron, OH	$28,081
11700	Asheville, NC	27,617
12420	Austin-Round Rock, TX	28,960
13140	Beaumont-Port Arthur, TX	32,544
17140	Cincinnati, OH-KY-IN	28,074
18580	Corpus Christi, TX	30,700

TABLE 1—CJR MANDATORY PARTICIPATION MSAS—Continued

MSA	MSA name	Wage-adjusted episode payments (in $)
20020	Dothan, AL	30,710
22500	Florence, SC	27,901
23540	Gainesville, FL	29,370
24780	Greenville, NC	27,446
25420	Harrisburg-Carlisle, PA	28,360
26300	Hot Springs, AR	29,621
28660	Killeen-Temple, TX	27,355
31080	Los Angeles-Long Beach-Anaheim, CA	28,219
31180	Lubbock, TX	29,524
32820	Memphis, TN-MS-AR	28,916
33100	Miami-Fort Lauderdale-West Palm Beach, FL	33,072
33740	Monroe, LA	30,431
33860	Montgomery, AL	30,817
35300	New Haven-Milford, CT	27,529
35380	New Orleans-Metairie, LA	29,562
35620	New York-Newark-Jersey City, NY-NJ-PA	31,076
36420	Oklahoma City, OK	27,267
36740	Orlando-Kissimmee-Sanford, FL	29,259
37860	Pensacola-Ferry Pass-Brent, FL	29,485
38300	Pittsburgh, PA	30,886
38940	Port St. Lucie, FL	30,423
39340	Provo-Orem, UT	28,852
39740	Reading, PA	28,679
42680	Sebastian-Vero Beach, FL	28,015
45300	Tampa-St. Petersburg-Clearwater, FL	32,424
45780	Toledo, OH	28,658
46220	Tuscaloosa, AL	31,789
46340	Tyler, TX	30,955

TABLE 2—CJR VOLUNTARY PARTICIPATION MSAS

MSA	MSA name	Wage-adjusted episode payments (in $)
10740	Albuquerque, NM	$25,892
12020	Athens-Clarke County, GA	25,394
13900	Bismarck, ND	22,479
14500	Boulder, CO	24,115
15380	Buffalo-Cheektowaga-Niagara Falls, NY	26,037
16020	Cape Girardeau, MO-IL	24,564
16180	Carson City, NV	26,128
16740	Charlotte-Concord-Gastonia, NC-SC	26,736
17860	Columbia, MO	25,558
19500	Decatur, IL	24,846
19740	Denver-Aurora-Lakewood, CO	26,119
20500	Durham-Chapel Hill, NC	25,151
22420	Flint, MI	24,807
23580	Gainesville, GA	23,009
26900	Indianapolis-Carmel-Anderson, IN	25,841
28140	Kansas City, MO-KS	27,261
30700	Lincoln, NE	27,173
31540	Madison, WI	24,442
33340	Milwaukee-Waukesha-West Allis, WI	25,698
33700	Modesto, CA	24,819
34940	Naples-Immokalee-Marco Island, FL	27,120
34980	Nashville-Davidson—Murfreesboro—Franklin, TN	26,880
35980	Norwich-New London, CT	25,780
36260	Ogden-Clearfield, UT	25,472
38900	Portland-Vancouver-Hillsboro, OR-WA	22,604
40980	Saginaw, MI	25,488
41180	St. Louis, MO-IL	26,425
41860	San Francisco-Oakland-Hayward, CA	23,716
42660	Seattle-Tacoma-Bellevue, WA	23,669
43780	South Bend-Mishawaka, IN-MI	23,143
44420	Staunton-Waynesboro, VA	25,539
45820	Topeka, KS	24,273
48620	Wichita, KS	25,945

TABLE 3—LOW-VOLUME HOSPITALS LOCATED IN THE MANDATORY MSAS ELIGIBLE TO OPT-IN DURING VOLUNTARY ELECTION PERIOD

CCN	Hospital name	MSA	MSA title
010034	Community Hospital, Inc	33860	Montgomery, AL.
010062	Wiregrass Medical Center	20020	Dothan, AL.
010095	Hale County Hospital	46220	Tuscaloosa, AL.
010097	Elmore Community Hospital	33860	Montgomery, AL.
010108	Prattville Baptist Hospital	33860	Montgomery, AL.
010109	Pickens County Medical Center	46220	Tuscaloosa, AL.
010149	Baptist Medical Center East	33860	Montgomery, AL.
040132	Leo N. Levi National Arthritis Hospital	26300	Hot Springs, AR.
050040	LAC-Olive View-UCLA Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050091	Community Hospital of Huntington Park	31080	Los Angeles-Long Beach-Anaheim, CA.
050137	Kaiser Foundation Hospital-Panorama City	31080	Los Angeles-Long Beach-Anaheim, CA.
050138	Kaiser Foundation Hospital-Los Angeles	31080	Los Angeles-Long Beach-Anaheim, CA.
050139	Kaiser Foundation Hospital-Downey	31080	Los Angeles-Long Beach-Anaheim, CA.
050158	Encino Hospital Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050205	Glendora Community Hospital	31080	Los Angeles-Long Beach-Anaheim, CA.
050373	LAC + USC Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050378	Pacifica Hospital of the Valley	31080	Los Angeles-Long Beach-Anaheim, CA.
050411	Kaiser Foundation Hospital-South Bay	31080	Los Angeles-Long Beach-Anaheim, CA.
050468	Memorial Hospital of Gardena	31080	Los Angeles-Long Beach-Anaheim, CA.
050543	College Hospital Costa Mesa	31080	Los Angeles-Long Beach-Anaheim, CA.
050548	Fairview Developmental Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050552	Motion Picture & Television Hospital	31080	Los Angeles-Long Beach-Anaheim, CA.
050561	Kaiser Foundation Hospital-West Los Angeles	31080	Los Angeles-Long Beach-Anaheim, CA.
050609	Kaiser Foundation Hospital-Orange County-Anaheim	31080	Los Angeles-Long Beach-Anaheim, CA.
050641	East Los Angeles Doctors Hospital	31080	Los Angeles-Long Beach-Anaheim, CA.
050677	Kaiser Foundation Hospital-Woodland Hills	31080	Los Angeles-Long Beach-Anaheim, CA.
050723	Kaiser Foundation Hospital-Baldwin Park	31080	Los Angeles-Long Beach-Anaheim, CA.
050738	Greater El Monte Community Hospital	31080	Los Angeles-Long Beach-Anaheim, CA.
050744	Anaheim Global Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050747	South Coast Global Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050751	Miracle Mile Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050771	Coast Plaza Hospital	31080	Los Angeles-Long Beach-Anaheim, CA.
050776	College Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050779	Martin Luther King Jr. Community Hospital	31080	Los Angeles-Long Beach-Anaheim, CA.
050780	Foothill Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA.
050782	Casa Colina Hospital	31080	Los Angeles-Long Beach-Anaheim, CA.
070038	Connecticut Hospice Inc	35300	New Haven-Milford, CT.
070039	Masonic Home and Hospital	35300	New Haven-Milford, CT.
100048	Jay Hospital	37860	Pensacola-Ferry Pass-Brent, FL.
100130	Lakeside Medical Center	33100	Miami-Fort Lauderdale-West Palm Beach, FL.
100240	Anne Bates Leach Eye Hospital	33100	Miami-Fort Lauderdale-West Palm Beach, FL.
100277	Douglas Gardens Hospital	33100	Miami-Fort Lauderdale-West Palm Beach, FL.
100320	Poinciana Medical Center	36740	Orlando-Kissimmee-Sanford, FL.
100326	Promise Hospital of Miami	33100	Miami-Fort Lauderdale-West Palm Beach, FL.
190005	University Medical Center New Orleans	35380	New Orleans-Metairie, LA.
190011	University Health Conway	33740	Monroe, LA.
190079	St. Charles Parish Hospital	35380	New Orleans-Metairie, LA.
190245	Monroe Surgical Hospital	33740	Monroe, LA.
190300	St. Charles Surgical Hospital LLC	35380	New Orleans-Metairie, LA.
190302	Omega Hospital LLC	35380	New Orleans-Metairie, LA.
190308	St. Bernard Parish Hospital	35380	New Orleans-Metairie, LA.
190313	New Orleans East Hospital	35380	New Orleans-Metairie, LA.
250012	Alliance Healthcare System	32820	Memphis, TN-MS-AR.
250126	North Oak Regional Medical Center	32820	Memphis, TN-MS-AR.
250167	Methodist Olive Branch Hospital	32820	Memphis, TN-MS-AR.
310058	Bergen Regional Medical Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330080	Lincoln Medical & Mental Health Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330086	Montefiore Mount Vernon Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA.
330100	New York Eye and Ear Infirmary	35620	New York-Newark-Jersey City, NY-NJ-PA.
330199	Metropolitan Hospital Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330231	Queens Hospital Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330233	Brookdale Hospital Medical Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330240	Harlem Hospital Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330385	North Central Bronx Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA.
330396	Woodhull Medical and Mental Health Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330397	Interfaith Medical Center	35620	New York-Newark-Jersey City, NY-NJ-PA.
330399	St. Barnabas Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA.
330405	Helen Hayes Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA.
360241	Edwin Shaw Rehab Institute	10420	Akron, OH.
370011	Mercy Hospital El Reno Inc	36420	Oklahoma City, OK
370158	Purcell Municipal Hospital	36420	Oklahoma City, OK.

TABLE 3—LOW-VOLUME HOSPITALS LOCATED IN THE MANDATORY MSAS ELIGIBLE TO OPT-IN DURING VOLUNTARY ELECTION PERIOD—Continued

CCN	Hospital name	MSA	MSA title
370199	Lakeside Women's Hospital A Member of INTEGRIS Health.	36420	Oklahoma City, OK.
370206	Oklahoma Spine Hospital	36420	Oklahoma City, OK.
370215	Oklahoma Heart Hospital	36420	Oklahoma City, OK.
370234	Oklahoma Heart Hospital South	36420	Oklahoma City, OK.
390184	Highlands Hospital	38300	Pittsburgh, PA.
390217	Excela Health Frick Hospital	38300	Pittsburgh, PA.
420057	McLeod Medical Center-Darlington	22500	Florence, SC.
420066	Lake City Community Hospital	22500	Florence, SC.
440131	Baptist Memorial Hospital Tipton	32820	Memphis, TN-MS-AR.
450143	Seton Smithville Regional Hospital	12420	Austin-Round Rock, TX.
450605	Care Regional Medical Center	18580	Corpus Christi, TX.
450690	University of Texas Health Science Center at Tyler	46340	Tyler, TX.
450865	Seton Southwest Hospital	12420	Austin-Round Rock, TX.
460043	Orem Community Hospital	39340	Provo-Orem, UT.
670087	Baylor Scott & White Emergency Medical Center-Cedar Park.	12420	Austin-Round Rock, TX.

As stated previously in this section, we proposed a one-time participation election period for all hospitals with a CCN primary address located in the voluntary participation MSAs listed in Table 2, low-volume hospitals specified in Table 3, and rural hospitals. Based on the anticipated timing for when this final rule implementing this proposal would be published, we proposed that the voluntary participation election period would begin January 1, 2018, and would end January 31, 2018. We noted that we must receive the participation election letter no later than January 31, 2018. We proposed that the hospital's participation election letter would serve as the model participant agreement. Voluntary participation would begin February 1, 2018, and continue through the end of the CJR model, unless sooner terminated. Thus, participant hospitals located in the voluntary participation MSAs listed in Table 2, the low-volume hospitals specified in Table 3, and the rural hospitals that elect voluntary participation would continue in the CJR model without any disruption to episodes attributed to performance year 3, which begins January 1, 2018. Participant hospitals located in the voluntary participation MSAs listed in Table 2, the low-volume hospitals specified in Table 3, and the rural hospitals that do not elect voluntary participation would be withdrawn from the model effective February 1, 2018, and all of their performance year 3 episodes up to and including that date would be canceled, so that these hospitals would not be subject to a reconciliation payment or repayment amount for performance year 3. We proposed to implement our proposed opt-in approach in this manner as a way to balance several goals, including establishing a uniform time period for hospitals to make a voluntary participation election, avoiding disruption of episodes for hospitals that elect to continue their participation in the CJR model, and preventing confusion about whether a hospital is participating in performance year 3 of the model. Specifically, we considered whether adopting a voluntary election period that ended prior to the start of performance year 3 would be less confusing and less administratively burdensome in terms of whether a hospital is participating in performance year 3. To implement this approach, the voluntary participation election period would have to close by December 31, 2017, such that each hospital would have made its determination regarding participation in performance year 3 before the start of performance year 3 (note that episodes attributed to performance year 3 would still be canceled under this alternative approach for eligible hospitals that do not make a participation election). We noted that because the voluntary election period under this approach would conclude in advance of the relevant CJR model performance year, this approach could simplify our administration of performance year 3 by establishing in advance of performance year 3 whether a hospital would be a participant hospital for the totality of performance year 3. However, given the timing of the proposed rulemaking, we were not confident that hospitals would have sufficient time to make a voluntary participation election by December 31, 2017. Thus, we proposed that the voluntary participation election period would occur during the first month of performance year 3 (that is, throughout January 2018) and would apply prospectively beginning on February 1, 2018. We believed this approach would best ensure adequate time for hospitals to make a participation election while minimizing the time period during which participation in performance year 3 remains mandatory for all eligible hospitals in the 67 selected MSAs. We noted that based on timing considerations, including potential changes to the anticipated date of publication of the final rule and interim final rule with comment period, we may modify the dates of the voluntary participation election period and make conforming changes to the dates for voluntary participation in performance year 3. We sought comment on the proposed voluntary participation election period, including whether we should instead require the participation election to be made by December 31, 2017 (that is, prior to the start of performance year 3) or if a different or later voluntary election period may be preferable.

Comment: Some commenters requested that we establish multiple opt-in periods. Several commenters requested an additional opt-in period after we announce new voluntary bundled payment initiatives, while others requested an annual opt-in process. Commenters also noted that they believe hospitals in the voluntary MSAs, as well as low volume and rural hospitals, do not have enough information to make an informed decision about participation in CJR at this time due to the following reasons: (1) We have not yet released details of the next voluntary bundled payment initiative; (2) January 1 through 31, 2018 is too soon for hospitals to make an educated decision; (3) it is unclear what, if any, revisions will be made to the CJR

pricing methodology if we finalize the proposed OPPS policy to remove total knee arthroplasty (TKA) from the inpatient-only (IPO) list; and (4) commenters believe that offering multiple opt-in periods will result in a great number of hospitals electing to remain in CJR.

Response: We appreciate commenters' concern that it may be more difficult for hospitals to make a participation decision during January 2018 given the uncertain factors that commenters provided. We understand that hospitals facing uncertainty for these reasons or others may choose not to opt-in based on that uncertainty. However, we believe that offering an opt-in period in January of 2018 is a reasonable timeframe, given the following reasons. First, hospitals opting-in to the model will have already been participants in CJR for nearly 2 years at that time. Participant hospitals have been receiving episode data and have received initial reconciliation results, and in many cases an initial reconciliation payment, for the first performance year of CJR. Second, as discussed in section II.I. of this final rule and interim final rule with comment period, we plan to address commenters' concerns about the potential impact of the removal of TKA from the IPO list in future rulemaking, as appropriate. Finally, we believe that a one-time opt-in process minimizes potential patient selection and gaming issues, as an annual opt-in process may result in hospitals only opting-in to the model if they are earning reconciliation payments. We also believe that a one-time opt-in process reduces confusion for hospitals regarding participation in the CJR model. We will publish a list on the CMS Web site of all hospitals participating in the CJR model for performance years 3 through 5 as of February 1, 2018. Therefore, we are finalizing our proposal to offer a one-time opt-in period for all participant hospitals in the 33 voluntary MSAs and rural and low volume hospitals in all 67 MSAs. In conjunction with the publication of this final rule and interim final rule with comment period, we will post on our Web site the list of rural hospitals we have identified as rural that will be automatically excluded from the CJR model if they do not submit an opt-in election as specified in this final rule and interim final rule with comment period. CJR hospitals not shown on this list who believe they should be considered rural should contact the CJR model at *CJR@cms.hhs.gov.*

Comment: A commenter was concerned about how the opt-in process would affect hospitals that have submitted a rural reclassification request prior to January 31, 2018 that has not yet been approved by CMS. The commenter requested that CMS notify all current CJR hospitals about the opt-in process, use the date the reclassification request was submitted to CMS to determine whether a hospital is rural, and offer a 30-day appeals process for hospitals with pending rural reclassification requests.

Response: We appreciate the commenter's recognition of the operational challenges involved in identifying which hospitals are rural hospitals for purposes of the model. For this reason, we proposed that we would consider a hospital's rural status as of January 31, 2018 for purposes of determining which hospitals are required to participate in CJR or are eligible for voluntary participation. We proposed, and are now notifying all CJR hospitals (and the public in general) about, the opt-in process. We also have included information about the proposed process, which we are now finalizing, in communications with current CJR participant hospitals. We do not believe it is appropriate, or in the best interest of rural hospitals, to offer an appeals process or additional opt-in periods for hospitals that reclassify to rural status, for the following reasons. First, we seek to minimize confusion as to which hospitals are in CJR and to avoid creating further incentives for hospitals to reclassify for reasons solely related to the CJR model. Second, any participant hospitals that are not reclassified as rural as of January 31, 2018 will have been participating in the CJR model since April 1, 2016 without rural status. Finally, participant hospitals have already had an incentive under the model to reclassify to rural, given that the CJR model has offered more limited financial risk for rural hospitals through lower stop-loss limits since downside risk began in year 2. We note that any participant hospital that reclassifies to rural after the opt-in period would have lower stop-loss limits for the remainder of the model. Thus, to more effectively operate the model, and to make it clear which hospitals will remain in CJR for performance years 3 through 5, we are finalizing our proposal to define rural hospitals for purposes of the model as those hospitals that have rural status as of the final day of the voluntary participation election period (January 31, 2018).

To specify their participation election, we proposed that hospitals would submit a written participation election letter to CMS in a form and manner specified by CMS. We noted that we intend to provide templates that can easily be completed and submitted in order to limit the burden on hospitals seeking to opt-in. If a hospital with a CCN primary address located in the voluntary participation MSAs or a low-volume or rural hospital in the mandatory participation MSAs does not submit a written participation election letter by January 31, 2018, the hospital's participation in performance year 3 would end, all of its performance year 3 episodes would be canceled, and it would not be included in the CJR model for performance years 4 and 5.

We proposed a number of requirements for the participation election letter and that the hospital's participation election letter would serve as the model participant agreement. First, we proposed that the participation election letter must include all of the following:

- Hospital Name.
- Hospital Address.
- Hospital CCN.
- Hospital contact name, telephone number, and email address.
- If selecting the Advanced APM track, attestation of CEHRT use as defined in § 414.1305.

Second, we proposed that the participation election letter must include a certification in a form and manner specific by CMS that—

- The hospital will comply with all requirements of the CJR model (that is, 42 CFR part 510) and all other laws and regulations that are applicable to its participation in the CJR model; and
- Any data or information submitted to CMS will be accurate, complete and truthful, including, but not limited to, the participation election letter and any quality data or other information that CMS uses in reconciliation processes or payment calculations or both.

We solicited feedback on this proposed certification requirement, including whether the certification should include different or additional attestations.

Finally, we proposed that the participation election letter be signed by the hospital administrator, chief financial officer (CFO) or chief executive officer (CEO).

We proposed that, if the hospital's participation election letter meets these criteria, we would accept the hospital's participation election. Once a participation election for the CJR model is made and is effective, the participant hospital would be required to participate in all activities related to the CJR model for the remainder of the CJR model unless the hospital's participation is terminated sooner.

Comment: Several commenters requested that we make the opt-in template available as soon as possible, and that the template be clear and concise, minimizing the administrative burden on hospitals and limiting confusion.

Response: We are finalizing the proposed elements of the participation election letter with one modification. We will not require hospitals to attest to CEHRT use in the opt-in template, as we currently request that information from hospitals on an annual basis, along with their clinician financial arrangements list, when they elect a track in CJR for purposes of Advanced APM status consistent with § 510.120. In order to minimize burden and limit confusion for hospitals as to whether attesting to CEHRT use in the opt-in template would supersede other information provided to use regarding CEHRT use, we are removing that item from the opt-in template. We note that the opt-in template for hospitals eligible for voluntary participation in CJR has been posted on the CMS public Web site at *https://innovation.cms.gov/initiatives/cjr* in conjunction with this final rule and interim final rule with comment period.

We noted that episodes end 90 days after discharge for the CJR model and episodes that do not start and end in the same calendar year will be attributed to the following performance year. For example, episodes that start in October 2017 and do not end on or before December 31, 2017 are attributed to performance year 3. Our methodology for attributing these episodes to the subsequent performance year would be problematic in cases where a hospital with a CCN primary address located in a voluntary participation MSA or a rural hospital or a low-volume hospital, as specified by CMS, has not elected to voluntarily continue participating in the model. Therefore, for a hospital with a CCN primary address located in a voluntary participation MSA, or a rural hospital or a low-volume hospital, as specified by CMS, that does not elect voluntary participation during the one-time voluntary participation election period, we proposed that all episodes attributed to performance year 3 for that hospital would be canceled and would not be included in payment reconciliation. Such hospitals would have their participation in the CJR model withdrawn effective February 1, 2018. We noted that this proposal is consistent with our policy for treatment of episodes that have not ended by or on the last day of performance year 5 and cannot be included in performance year 5 reconciliation due to the end of the model (see Table 8 of the CJR model final rule (80 FR 73326)).

We stated that we believe our proposed opt-in approach to allow for voluntary participation in the CJR model by certain hospitals would be less burdensome on such hospitals than a potential alternative approach of requiring hospitals to opt-out of the model. In developing the proposal to allow eligible hospitals located in the proposed 33 voluntary participation MSAs and low-volume and rural hospitals located in the 34 mandatory participation MSAs to elect voluntary participation, we considered whether to propose that hospitals would have to make an affirmative voluntary participation election (that is, an opt-in approach) or to propose that these hospitals would continue to be required to participate in the CJR model unless written notification was given to CMS to withdraw the hospital from the CJR model (that is, an opt-out approach). We stated that we believe an opt-in approach would be less burdensome on hospitals, because it would not require participation in the CJR model for hospitals located in the proposed 33 voluntary participation MSAs and for low-volume and rural hospitals located in the 34 mandatory participation MSAs unless the hospital affirmatively chose it. Further, we stated that we believe requiring an affirmative opt-in election would result in less ambiguity about a hospital's participation intentions as compared to an opt-out approach. Specifically, with an opt-in approach, a hospital's participation election would document each hospital's choice, whereas under an opt-out approach there could be instances where hospitals fail to timely notify CMS of their desire to withdraw from participation and are thus included in the model and subject to potential repayment amounts. For these reasons, we proposed an opt-in approach. We sought comment on this proposal and the alternative considered.

Comment: A commenter requested that CMS clarify whether hospitals are allowed to terminate participation in CJR. The commenter noted that although our proposal for the opt-in process is clear, the language in the proposed rule does not clearly state whether a hospital could opt-in to CJR and later opt-out of the model after January 2018. Another commenter requested clarification as to whether a hospital that opts-in to CJR may later withdraw from the model through participation in a new voluntary bundled payment initiative.

Response: Under our proposed policy, all hospitals that opt-in to the model as of January 31, 2018 would be required to participate through the end of performance year 5 (episodes that end by December 31, 2020), unless such participation were terminated in accordance with § 510.410 or § 510.900, regardless of the hospital's participation in a new voluntary bundled payment initiative.

A summary of the finalized changes to the CJR model participation requirements is shown in Table 4.

Summary of Final Decisions: We are finalizing our proposals to reduce the number of MSAs where all IPPS hospitals are required to participate in CJR from 67 to 34, and to allow for voluntary participation for all IPPS participant hospitals in the remaining 33 MSAs. We are also finalizing our proposal that rural hospitals (as defined at § 510.2 as of January 31, 2018) and low volume hospitals, defined as hospitals with fewer than 20 episodes in the historical baseline period used to create the PY1 target prices, in the 34 mandatory participation MSAs are not required to participate in the model but may opt-in to the model. We are finalizing our proposal to offer a single opt-in period from January 1, 2018 through January 31, 2018. Table 4 provides a summary of our final participation requirements.

These policies are codified at §§ 510.2, 510.105, and 510.115.

TABLE 4—PARTICIPATION REQUIREMENTS FOR HOSPITALS IN THE CJR MODEL

	Required to participate as of February 1, 2018	May elect voluntary participation	Participation election period	Election effective date
Mandatory Participation MSAs				
All IPPS participant hospitals, except rural and low-volume *	Yes	No	n/a	n/a
Rural hospitals *	No	Yes	1/1/2018–1/31/2018	2/1/2018

TABLE 4—PARTICIPATION REQUIREMENTS FOR HOSPITALS IN THE CJR MODEL—Continued

	Required to participate as of February 1, 2018	May elect voluntary participation	Participation election period	Election effective date
Low-volume hospitals (see Table 3)	No	Yes	1/1/2018–1/31/2018	2/1/2018
Voluntary Participation MSAs				
All IPPS participant hospitals	No	Yes	1/1/2018–1/31/2018	2/1/2018

* **Note:** Participation requirements are based on the CCN status of the hospital as of January 31, 2018. A change in rural status after the voluntary election period does not affect the participation requirements.

2. Proposed Codification of CJR Model-Related Evaluation Participation Requirements

We note that for the CJR model evaluation, the data collection methods and key evaluation research questions under the proposed reformulated approach (that is, the proposal for voluntary opt-in elections discussed in section III.B.1. of the proposed rule (82 FR 39313)) would remain similar to the approach presented in the CJR model final rule. The evaluation methodology for the CJR model would be consistent with the standard Innovation Center approaches we have taken in other voluntary models such as the Pioneer Accountable Care Organization (ACO) Model. Cooperation and participation in model-related activities by all hospitals that participate in the CJR model would continue to be extremely important to the evaluation. Therefore, with respect to model-related evaluation activities, we proposed to add provisions in § 510.410(b)(1)(i)(G) to specify that CMS may take remedial action if a participant hospital, or one of its collaborators, collaboration agents, or downstream collaboration agents fails to participate in model-related evaluation activities conducted by CMS and/or its contractors for any performance year in which the hospital participates. We noted that we believe the addition of this provision would make participation and collaboration requirements for the CJR model evaluation clear to all participant hospitals and in particular to hospitals that are eligible to elect voluntary participation. We sought comment on our proposed regulatory change.

Comment: A commenter requested clarification on our proposal, including how CMS will monitor hospitals for compliance, what the remedial actions will be, and if the evaluation requirements apply to collaborators as well.

Response: In order to monitor whether hospitals comply with the model's evaluation requirements, we may do so through our existing monitoring activities, which include data analysis and other methods such as site visits and interviews, or through other methods. Under the existing CJR model regulations, we have numerous remedial actions available to us, should a hospital fail to comply with any of the model requirements. We believe that our ability to evaluate the CJR model is a crucial aspect of the model test, and therefore we are finalizing our proposal to add provisions to § 510.410(b)(1)(i)(G) to specify that we may take remedial action if a CJR participant hospital, collaborator, collaboration agent, or downstream collaboration agent fails to comply with model-related evaluation activities. We refer readers to section § 510.410(b)(2) of the CJR regulations for a list of potential remedial actions. Finally, we note that our regulations at § 510.410 state that model requirements such as the addition of evaluation requirements apply to CJR collaborators as well as participant hospitals.

3. Comment Solicitation: Incentivizing Participation in the CJR Model

In the August 17, 2017 proposed rule (82 FR 39310 through 39333), we proposed to make participation in the CJR model voluntary in 33 MSAs and for low-volume and rural hospitals in the remaining 34 MSAs via the proposed opt-in election policy discussed in section III.B.1 of the proposed rule (82 FR 39313). In order to keep hospitals in all MSAs selected for participation in the CJR model actively participating in the model, we solicited comment on ways to further incentivize eligible hospitals to elect to continue participating in the CJR model for the remaining years of the model and to further incentivize all participant hospitals to advance care improvements, innovation, and quality for beneficiaries throughout LEJR episodes.

Comment: Commenters suggested a variety of ways that CMS could incentivize participation in the CJR model, and in bundled payment models in general, including: Allowing convener organizations, including medical device manufacturers, to participate in CJR; limiting model participation to entities that provide direct patient care; reducing the regional component of CJR target prices in performance years 3 through 5 of the model; setting target prices at the higher of the hospital-specific or regional amount; using MSAs instead of U.S. Census Divisions to establish regional pricing; avoiding rebasing prices near the beginning of the model; limiting the use of a national trend factor to avoid penalizing hospitals that have reduced episode spending under models like BPCI; including reconciliation and repayment amounts in target prices; including risk adjustment in the pricing methodology, including adjustment for socioeconomic factors; allowing gainsharing on a more frequent basis; excluding further procedures and diagnoses, such as cancer, from CJR model episodes; altering the pricing structure to ensure that high-performing hospitals are incentivized to remain in the model as it moves to regional pricing and baseline years are updated to include later years; allow hospitals to choose when they enter downside risk; annually evaluating whether models should include outpatient procedures; changing precedence rules to level the playing field for hospitals; broadening CJR to allow other entities such as physicians and non-IPPS providers such as inpatient rehabilitation facilities to initiate episodes and bear direct financial risk for episode spending; offering waivers of certain IRF payment policies to allow for additional flexibilities for post-acute care providers; and releasing baseline data and target prices in advance of model start dates.

Response: We thank the commenters for their suggestions to incentivize participation in CJR and in bundled payment models in general. We note that we have considered and discussed some of these suggestions and issues in prior rulemaking that established the CJR model regulations (see 80 FR 73273). We will continue to consider

these options raised by commenters as we move forward with CJR and other models.

Additionally, we noted in the August 17, 2017 proposed rule that, under the CJR refinements established in the January 3, 2017 EPM final rule, the total amount of gainsharing payments for a performance year paid to physicians, non-physician practitioners, physician group practices (PGPs), and non-physician practitioner group practices (NPPGPs) must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for items and services that are furnished to beneficiaries during episodes that occurred during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made (§ 510.500(c)(4)). Distribution payments to these individuals and entities are similarly limited as specified in § 510.505(b)(8), and downstream distribution payments are similarly limited as specified in § 510.506(b)(8). These program integrity safeguards, which are consistent with the gainsharing caps in other Innovation Center models, were included to avoid setting an inappropriate financial incentive that may result in stinting, steering or denial of medically necessary care (80 FR 73415 and 73416). While we did not propose in the August 17, 2017 proposed rule any changes to the gainsharing caps for these models, we noted that we had heard various opinions from stakeholders, including the Medicare Payment Advisory Commission (MedPAC), on the relative benefit of such limitations on gainsharing and in the proposed rule we solicited comment on this requirement and any alternative gainsharing caps that may be appropriate to apply to physicians, non-physician practitioners, PGPs, and NPPGPs.

Comment: Several commenters supported the current 50 percent gainsharing cap. Other commenters offered a variety of recommendations for changing the gainsharing limitations, including: Increasing the frequency of gainsharing payments from hospitals to collaborators; increasing the gainsharing cap on physicians, non-physician practitioners, PGPs, and NPPGPs to 70 percent; granting hospitals increased flexibility in designing their respective gainsharing programs and determining the amount of savings to share with their collaborators; removing all gainsharing limits, noting that when surgeons coordinate with the hospital to provide efficient, high-quality care that decreases cost, they should be able to fully share in the resulting cost reductions; providing more clarity on the applicability of the gainsharing policy; and coordinating unified guidance from CMS and the HHS Office of the Inspector General (OIG) relating to gainsharing and the model's fraud and abuse waivers, as well as providing a mechanism for hospitals to ask questions about the model's waivers.

Response: We thank the commenters for their suggestions regarding gainsharing limitations and alternative gainsharing caps. We will continue to consider these issues raised by commenters as we move forward with CJR and other models.

Comments on the waivers of fraud and abuse laws for the CJR model are beyond the scope of this rulemaking. Fraud and abuse waivers issued in connection with the CJR model are available at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html* and on the OIG's Web site. No waivers of any fraud and abuse authorities are being issued in this final rule.

C. Maintaining ICD–CM Codes for Quality Measures

In the CJR model final rule (80 FR 73474), we discussed how specific International Classification of Diseases (ICD)—Clinical Modifications (CM) procedure codes define group of procedures included in the Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications) measure. In discussing quality measures in general, the ICD–CM codes relative to defining a measure cohort are updated annually and are subject to change. For example, in the EPM final rule (82 FR 389), we itemized specific ICD–9–CM and ICD–10–CM codes for Hip/Knee Complications measure. As quality measures are refined and maintained, the ICD–CM code values used to identify the relevant diagnosis and/or procedures included in quality measures can be updated. For example, CMS' Center for Clinical Standards and Quality (CCSQ) has recently updated the list of ICD–10 codes used to identify procedures included in the Hip/Knee Complications measure. We did not intend for our preamble discussions of certain ICD–CM codes used, for example, to identify procedures included in the Hip/Knee Complications measures, and therefore the PRO cohorts for the CJR model, to set a policy that would define the relevant cohorts for the entirety of the CJR model. We should have also directed readers to look for the most current codes on the CMS quality Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* To ensure that model participants are aware of periodic ICD–CM code updates to the Hip/Knee Complications measure, we proposed to clarify that participants must use the applicable ICD–CM code set that is updated and released to the public each calendar year in April by CCSQ and posted on the Hospital Quality Initiative Measure Methodology Web site (*https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*) for purposes of reporting each of those measures.

CMS relies on the National Quality Forum (NQF) measure maintenance update and review processes to update substantive aspects of measures every 3 years. Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measures. Examples of such changes include updated diagnosis or procedures codes, changes to patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes and do not require the use of the agency's regulatory process used to update more detailed aspects of quality measures.

Final Decision: We did not receive any comments regarding this section. Therefore, we are finalizing the proposal without modification.

D. Clarification of CJR Reconciliation Following Hospital Reorganization Event

In the CJR model final rule (80 FR 73348) rule, we discussed our method of setting target prices using all historical episodes that would represent our best estimate of historical volume and payments for participant hospitals when an acquisition, merger, divestiture, or other reorganization results in a hospital with a new CCN. When a reorganization event occurs during a performance year, CMS updates the quality-adjusted episode target prices for the new or surviving participant hospital (§ 510.300(b)(4)). Following the end of a performance year, CMS performs annual reconciliation calculations in accordance with the provisions established in § 510.305. The annual reconciliation calculations are specific

to the episodes attributable to each participant hospital entity for that performance year. The applicable quality-adjusted episode target price for such episodes is the quality-adjusted episode target price that applies to the episode type as of the anchor hospitalization admission date (§ 510.300(a)(3)). For example, if during a performance year, two participant hospitals (Hospital A and Hospital B) merge under the CCN of one of those two participant hospital's CCN (Hospital B's CCN), (assuming no other considerations apply) three initial (and three subsequent) annual reconciliation calculations for that performance year are performed: An initial (and subsequent) reconciliation for Hospital A for the episodes where the anchor hospitalization admission occurred prior to the merger (as determined by the CCN on the IPPS claim), using Hospital A's episode target price for that time period; an initial (and subsequent) reconciliation for Hospital B for the episodes where anchor hospitalization admission occurred before the merger (as determined by the CCN on the IPPS claim), using Hospital B's episode target price for that time period; and an initial (and subsequent) reconciliation for the post-merger entity (merged Hospitals A and B) for the episodes where anchor hospitalization admission occurred on or after the merger's effective date, using the episode target price for that time period. Reorganization events that involve a CJR participant hospital and a hospital that is not participating in the CJR model and result in the new organization operating under the CJR participant hospital's CCN, would not affect the reconciliation for the CJR participant hospital for episodes that initiate before the effective date of the reorganization event. Episodes that initiate after such reorganization event would be subject to an updated quality-adjusted episode target price that is based on historical episodes for the CJR participant hospital which would include historical episode expenditures for all hospitals that are integrated under the surviving CCN. These policies have been in effect since the start of the CJR model on April 1, 2016. To further clarify this policy for the CJR model, we proposed to add a provision specifying that separate reconciliation calculations are performed for episodes that occur before and after a reorganization that results in a hospital with a new CCN at § 510.305(d)(1). We noted that we believe this clarification would increase transparency and understanding of the payment reconciliation processes for the CJR model. We sought comment on this proposal.

Comment: We received no comments on our proposal.

Response: We will finalize this proposal without modification. We will continue to perform two reconciliation calculations for hospitals that undergo a merger, consistent with our existing regulations.

E. Proposed Adjustment to the Pricing Calculation for the CJR Telehealth HCPCS Codes To Include the Facility PE Values

In the CJR model final rule (80 FR 73450), we established 9 HCPCS G-codes to report home telehealth evaluation and management (E/M) visits furnished under the CJR telehealth waiver as displayed in Table 5. These codes have been payable for CJR model beneficiaries since the CJR model began on April 1, 2016. Pricing for these 9 codes is updated each calendar year to reflect the work and malpractice (MP) relative value units (RVUs) for the comparable office and other outpatient E/M visit codes on the Medicare Physician Fee Schedule (MPFS). As we stated in the CJR model final rule (80 FR 73450), in finalizing this pricing method for these codes, we did not include the practice expense (PE) RVUs of the comparable office and other outpatient E/M visit codes in the payment rate for these unique CJR model services, based on the belief that practice expenses incurred to furnish these services are marginal or are paid for through other MPFS services. However, since the publication of the CJR model final rule, stakeholders have expressed concern that the zero value assigned to the PE RVUs for these codes results in inaccurate pricing. Stakeholders assert that there are additional costs related to the delivery of telehealth services under the CJR model such as maintaining the telecommunications equipment, software and security and that, while these practice expense costs are not equivalent to in-person service delivery costs, they are greater than zero. In considering the pricing concerns voiced by stakeholders, we recognized that there are resource costs in practice expense for telehealth services furnished remotely. However, we did not believe the current PE methodology and data accurately accounted for these costs relative to the PE resource costs for other services. This belief previously led us to assign zero PE RVUs in valuing these services, but because we recognized that there are some costs that were not being accounted for by the current pricing for these CJR model codes, we believed an alternative to assigning zero PE RVUs would be to use the facility PE RVUs for the analogous in-person services. While we acknowledged that assigning the facility PE RVUs would not provide a perfect reflection of practice resource costs for remote telehealth services under the CJR model, in the absence of more specific information, we believed it was likely a better proxy for such PE costs than zero. Therefore, we proposed to use the facility PE RVUs for the analogous services in pricing the 9 CJR HCPCS G codes shown in Table 5. Additionally, we proposed to revise § 510.605(c)(2) to reflect the addition of the RVUs for comparable codes for the facility PE to the work and MP RVUs we are currently using for the basis for payment of the CJR telehealth waiver G codes.

Comment: Commenters supported CMS' proposal to assign facility PE RVUs to the telehealth codes utilized under the CJR model, stating that our proposal acknowledges the additional infrastructure and care coordination costs associated with providing telehealth services and supports increasing the use of telemedicine for Medicare beneficiaries. A commenter requested that CMS allow physical therapists to furnish telehealth services under CJR. Another commenter requested that CMS develop a demonstration to test whether capitated payments may increase the utilization of telehealth services.

Response: We thank the commenters for their support of our proposed policy. We note that we did not propose to make any changes to the regulations regarding providers and suppliers that may furnish telehealth services under CJR. We agree that, while the PE values are not a perfect representation of the overhead costs associated with furnishing telehealth services, they are a reasonable approximation of the care coordination and infrastructure costs. We are finalizing our proposed policy to use the facility PE RVUs for analogous services when pricing the 9 HCPCS G-codes used for telehealth services under the CJR model. We also thank commenters for their suggestions around incentivizing the use of telehealth more generally.

This policy is codified in the regulations at § 510.605 (which we inadvertently referred to as § 510.65 in the proposed rule).

TABLE 5—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 PFS; PE RVUs equal to the facility values for each
G9481	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components: • A problem focused history. • A problem focused examination. • 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 new pt 10 mins ...	99201
G9482	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components: • An expanded problem focused history. • An expanded problem focused examination. • Straightforward medical decision-making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified healthcare 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 20 mins ...	99202
G9483	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components: • A detailed history. • A detailed examination. • 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 healthcare 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 30 mins ...	99203
G9484	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components:	Remote E/M new pt 45 mins ...	99204

TABLE 5—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 PFS; PE RVUs equal to the facility values for each
	• A comprehensive history. • A comprehensive examination. • 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 healthcare 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.		
G9485	Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components: • A comprehensive history. • A comprehensive examination. • 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 healthcare 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 60 mins	99205
G9486	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components: • A problem focused history. • A problem focused examination. • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified healthcare 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 10 mins	99212
G9487	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components:	Remote E/M est. pt 15 mins	99213

TABLE 5—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 PFS; PE RVUs equal to the facility values for each
	• An expanded problem focused history. • An expanded problem focused examination. • 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 healthcare 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.		
G9488	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components: • A detailed history. • A detailed examination. • 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 healthcare 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 25 mins	99214
G9489	Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components: • A comprehensive history. • A comprehensive examination. • 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 healthcare 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 40 mins	99215

F. Clinician Engagement Lists

1. Background for Submission of Clinician Engagement Lists

Under the Quality Payment Program, the Advanced APM track of the CJR model does not include eligible clinicians on a Participation List; rather the CJR Advanced APM track currently includes eligible clinicians on an Affiliated Practitioner List as defined under § 414.1305 and described under § 414.1425(a)(2) of the agency's Quality Payment Program regulations. As such, the Affiliated Practitioner List for the CJR model is the ''CMS-maintained list'' of eligible clinicians that have ''a contractual relationship with the Advanced APM Entity [for CJR, the participant hospital] for the purposes of supporting the Advanced APM Entity's quality or cost goals under the Advanced APM.'' As specified in our regulations at § 414.1425(a)(2), CMS will use this list to identify the eligible clinicians who will be assessed as Qualifying APM Participants (QPs) for the year. CMS will make QP determinations individually for these eligible clinicians as specified in §§ 414.1425(b)(2), (c)(4), and 414.1435.

In the EPM final rule, we stated that a list of physicians, nonphysician practitioners, or therapists in a sharing arrangement, distribution arrangement, or downstream distribution

arrangement, as applicable, would be considered an Affiliated Practitioner List of eligible clinicians who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM for purposes of the Quality Payment Program. An in-depth discussion of how the clinician financial arrangement list is considered an Affiliated Practitioner List can be found in section V.O. of the EPM final rule (82 FR 558 through 563). The clinician financial arrangements list (§ 510.120(b)) will be used by CMS to identify eligible clinicians for whom we would make a QP determination based on services furnished through the Advanced APM track of the CJR model.

2. Proposed Clinician Engagement List Requirements

To increase opportunities for eligible clinicians supporting CJR model participant hospitals by performing CJR model activities and who are affiliated with participant hospitals to be considered QPs, we proposed that each physician, nonphysician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS, but who does have a contractual relationship with the participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the performance year specified by CMS, would be added to a clinician engagement list.

In addition to the clinician financial arrangement list that is considered an Affiliated Practitioner List for purposes of the Quality Payment Program, we proposed the clinician engagement list would also be considered an Affiliated Practitioner List. The clinician engagement list and the clinician financial arrangement list would be considered together an Affiliated Practitioner List and would be used by CMS to identify eligible clinicians for whom we would make a QP determination based on services furnished through the Advanced APM track of the CJR model. As specified in § 414.1425, as of our regulations, adopted in the Calendar Year (CY) 2017 Quality Payment Program final rule (81 FR 77551), those physicians, nonphysician practitioners, or therapists who are included on the CJR model Affiliated Practitioner List as of March 31, June 30, or August 31 of a QP performance period would be assessed to determine their QP status for the year. As discussed in the 2017 Quality Payment Program final rule (81 FR 77439 and 77440), for clinicians on an Affiliated Practitioner List, we determined whether clinicians meet the payment amount or patient count thresholds to be considered QPs (or Partial QPs) for a year by evaluating whether individual clinicians on an Affiliated Practitioner List have sufficient payments or patients flowing through the Advanced APM; we do not make any determination at the APM Entity level for Advanced APMs in which eligible clinicians are not identified on a Participation List, but are identified on an Affiliated Practitioner List. CMS makes the QP determination based on Part B claims data, so clinicians need not track or report payment amount or patient count information to CMS.

We noted that the proposal to establish a clinician engagement list would broaden the scope of eligible clinicians that are considered Affiliated Practitioners under the CJR model to include those without a financial arrangement under the CJR model but who are either directly employed by or contractually engaged with a participant hospital to perform clinical work for the participant hospital when that clinical work, at least in part, supports the cost and quality goals of the CJR model. We proposed that the cost and quality goals of the additional affiliated practitioners who are identified on a clinician engagement list because they are contracted with a participant hospital must include activities related to CJR model activities. CJR model activities are activities related to promoting accountability for the quality, cost, and overall care for beneficiaries during LEJR episodes included in the CJR model, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during a CJR episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the CJR model.

Like the requirements of the clinician financial arrangement lists specified at § 510.120(b), for CMS to make QP determinations for eligible clinicians based on services furnished through the CJR Advanced APM track, we would require that accurate information about each physician, non-physician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS, but who is included on a clinician engagement list, be provided to CMS in a form and manner specified by CMS on a no more than quarterly basis. Thus, we proposed that each participant hospital in the Advanced APM track of the CJR model submit to CMS a clinician engagement list in a form and manner specified by CMS on a no more than quarterly basis. We proposed this list must include the following information on eligible clinicians for the period of the CJR model performance year specified by CMS:

- For each physician, non-physician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS but who does have a contractual relationship with a participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the CJR model performance year specified by CMS:

++ The name, TIN, and NPI of the individual.

++ The start date and, if applicable, the end date for the contractual relationship between the individual and participant hospital.

Further, we proposed that if there are no individuals that meet the requirements to be reported, as specified in any of § 510.120 (b)(1) through (3) of the EPM final rule or § 510.120(c) of the August 17, 2017 proposed rule (82 FR 39310 through 39333), the participant hospital must attest in a form and manner required by CMS that there are no individuals to report.

Given that the proposal would require submission of a clinician engagement list, or an attestation that there are no eligible clinicians to be included on such a list, to reduce burden on participant hospitals, we would collect information for the clinician engagement list and clinician financial arrangement list at the same time.

We sought comments on the proposal for submission of this information. We noted that we were especially interested in comments about approaches to information submission, including the periodicity and method of submission to CMS that would minimize the reporting burden on participant hospitals while providing CMS with sufficient information about eligible clinicians to facilitate QP determinations.

For each participant hospital in the CJR Advanced APM track, we proposed that the participant hospital must maintain copies of its clinician engagement lists and supporting documentation (that is, copies of employment letters or contracts) of its clinical engagement lists submitted to CMS. Because we would use these lists to develop Affiliated Practitioner Lists used for purposes of making QP

determinations, these documents would be necessary to assess the completeness and accuracy of materials submitted by a participant hospital and to facilitate monitoring and audits. For the same reason, we further proposed that the participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

Comment: Many commenters supported our proposal to broaden the scope of eligible clinicians that could be considered Affiliated Practitioners under the CJR model and therefore eligible for the incentives available under the Advanced APM track of the Quality Payment Program. Commenters urged CMS to finalize the policy as proposed, stressing the importance of providing further opportunities for clinician groups to engage in more comprehensive risk-based Advanced APMs as an alternative to MIPS reporting. Commenters also stated that a significant number of healthcare clinicians support participant hospitals but their efforts are not accounted for by CMS, despite the critical importance of the care they deliver to patients included within the CJR model. These commenters noted that expanding the number of Affiliated Practitioners will help to recognize the efforts of those clinicians while also enhancing access to care under the CJR model.

Response: We appreciate the positive feedback on the proposed policy, and agree with commenters that increasing opportunities for clinicians in a contractual relationship with Advanced APM participant hospitals is valuable. We agree that the work these clinicians perform on CJR model activities is essential to the success of care under the CJR model and that we should be recognizing the efforts of these clinicians by providing them the opportunity to qualify as qualified practitioners under the Quality Payment Program.

Comment: A commenter requested that CMS provide clarification on the definition of contractual agreements, and that CMS provide further guidance on how CJR-related activities will be monitored and whether there will be any thresholds that clinicians must meet to be considered engaged in the quality or costs goals of CJR.

Response: To clarify, for each physician, non-physician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS, but who does have a contractual relationship with the participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the performance year as specified by CMS, can be included on the hospital's clinician engagement list. The term contractual relationship encompasses the wide range of relationships whereby a participant hospital engages a clinician to perform work that at least in part supports the cost and quality goals of the CJR model

CMS will monitor compliance with the requirement that clinicians be engaged to support cost and quality goals via a range of methods, including but not limited to document reviews and site visits.

CMS is not establishing a specific threshold a clinician must met to be considered engaged in supporting the cost and quality goals of the CJR model.

Comment: Several commenters objected to the requirement that hospitals include a clinician's start and end date on the clinician engagement list, noting a start date is not feasible because the clinician's employment may have started before the start of the CJR model and may not have end-dates but rather automatically renew. Commenters also stated that maintaining and submitting a clinician engagement list is burdensome. The commenters suggested that hospitals should attest that the clinician was under contract during the model, and that CMS could conduct audits to verify this information.

Response: We appreciate commenters' feedback on this requirement for submitting the clinician engagement list. The requirement that a hospital include the clinician's start date at a minimum will allow CMS to determine whether the clinician is an eligible clinician for Quality Payment Program purposes; a simple attestation will not suffice for the Quality Payment Program. We understand that clinicians may have begun the contractual relationship with the hospital prior to the start of the CJR model. However, the hospital will have to determine whether and when the contractual relationship with the clinician began supporting the participant hospital's quality or cost goals under the CJR model. The hospital would then report to CMS the date on which the relationship began supporting the cost and quality goals of the CJR model. For example, if a physician started working at the participant hospital on 1/1/2000 and started supporting the participant hospital's quality or cost goals under the CJR model on 7/15/2016, the hospital would report 7/15/2016. The end date of the contractual relationship need only be supplied if the clinician has one. Also, we understand that maintaining a list can be burdensome; however, we developed this requirement in response to feedback from stakeholders and hospitals who expressed a desire to enhance opportunities for those physicians, non-physician practitioners, and therapists without a financial arrangement under the CJR model. Finally, in order to reduce burden, CMS will collect information for the clinician financial arrangement list and the clinician engagement list together. Hospitals will be able to complete all required attestations at one time.

Summary of Final Decisions: We thank the commenters for their suggestions and feedback. We are finalizing our policy as proposed. This policy is codified at § 510.120(c) through (e).

G. Clarification of Use of Amended Composite Quality Score Methodology During CJR Model Performance Year 1 Subsequent Reconciliation

We conducted the initial reconciliation for performance year 1 of the CJR model in early 2017 and made reconciliation payments to CJR participant hospitals in fall 2017 to accommodate the performance year 1 appeals process timelines. We will conduct the subsequent reconciliation calculation for performance year 1 of the CJR model beginning in the first quarter of 2018, which may result in additional amounts to be paid to participant hospitals or a reduction to the amount that was paid for performance year 1. However, the results of the performance year 1 subsequent reconciliation calculations will be combined with the performance year 2 initial reconciliation results before reconciliation payment or repayment amounts are processed for payment or collection. Changes to the CJR model established in the EPM final rule impact this process.

The improvements to the CJR model quality measures and composite quality score methodology, which were finalized in the EPM final rule (82 FR 524 through 526), were intended to be effective before the CJR model's performance year 1 initial reconciliation. However, as noted in section II. of the proposed rule (82 FR 39311), the effective date for certain EPM final rule provisions, including those amending §§ 510.305 and 510.315 to improve the quality measures and composite quality score methodology, were delayed until May 20, 2017.

As a result, the CJR reconciliation reports issued in April 2017 were created in accordance with the provisions of §§ 510.305 and 510.315 in effect as of April 2017; that is, the

provisions finalized in the CJR model final rule. In early 2018, we would perform the performance year 1 subsequent reconciliation calculation in accordance with the provisions §§ 510.305 and 510.315 in effect as of early 2018, that is, established in the EPM final rule. Applying the provisions established in the EPM final rule to the performance year 1 subsequent reconciliation calculation may result in significant differences between the reconciliation payments calculated during the performance year 1 initial reconciliation and the performance year 1 subsequent reconciliation. We anticipate that these differences will be greater than those that would be expected as a result of using more complete claims and programmatic data that will be available for the subsequent reconciliation (due to the additional 12 months of time that will occur between the initial and subsequent reconciliation calculations), more accurate identification of model overlap and exclusion of episodes, as well as factoring in adjustments to account for shared savings payments, and post-episode spending, as specified in § 510.305(i).

Specifically, the methodology used to determine the quality-adjusted target price for the performance year 1 subsequent reconciliation calculation would differ from the methodology used to determine the quality-adjusted target price for the performance year 1 initial reconciliation calculation as follows: The quality-adjusted target price would be recalculated to apply the amended reductions to the effective discount factors (§ 510.315(f)), which would be determined after recalculating the composite quality scores, including applying more generous criteria for earning quality improvement points (that is, a 2 decile improvement rather than 3 decile improvement as specified in amended § 510.315(d)). Using the recalculated quality-adjusted target price, the net payment reconciliation amount (NPRA) would be recalculated and include application of post-episode spending reductions (§ 510.305(j)), as necessary, after determining the limitations on loss or gain. Thus, calculating performance year 1 reconciliation payments using these two different provisions may result in a range of upward or downward adjustments to participant hospitals' performance year 1 payment amounts. We note that a downward adjustment to the performance year 1 payment amounts would require payment recoupment, if offset against a performance year 2 initial reconciliation payment amount is not feasible, which may be burdensome for participant hospitals.

In developing the August 17, 2017 proposed rule (82 FR 39310 through 39333), we also considered whether there might be benefit in further delaying the amendments to §§ 510.305 and 510.315 such that the same calculations would be used for both the performance year 1 initial reconciliation and the subsequent performance year 1 reconciliation, and the use of the amended calculations would begin with the performance year 2 initial reconciliation. We noted that we believe such an approach would impact future CJR model implementation and evaluation activities. Because determining the performance year 2 composite quality score considers the hospital's quality score improvement from its performance year 1 score, using different methodologies across performance years would require a mechanism to account for differences in the quality score methodology, for example we would have to develop a reliable crosswalk approach. If we were to develop and use a crosswalk approach, participants and other stakeholders would need to be informed about the crosswalk methodology in order to validate data analyses across performance years and that usage of the crosswalk would be ongoing throughout the model's duration for consistency across performance years. This methodology could add substantial complexity to this time-limited model. We also considered that the composite quality score for some participant hospitals may be higher under the revised scoring methodology. Delaying use of the revised scoring methodology may disadvantage participants if their composite quality score would be higher and result in a more favorable discount percentage or allow the hospital to qualify for a reconciliation payment. Therefore, we believed the best approach was to apply the quality specifications as established in the EPM final rule (that is, the amendments to §§ 510.305 and 510.315 that became effective May 20, 2017) to performance year 1 subsequent reconciliation calculations to ensure that reconciliation calculations for subsequent performance years will be calculated using the same methodology and to improve consistency across performance years for quality improvement measurement. Thus, for the reasons noted previously, we did not propose to change the amendments to §§ 510.305 and 510.315 that became effective May 20, 2017. We sought comment on whether using an alternative approach, such as the composite quality score methodology from the CJR model final rule for the performance year 1 subsequent reconciliation, would ensure better consistency for analyses across CJR performance years.

Comment: We received several comments supporting our proposal to apply the quality specifications as established in the EPM final rule (that is, the amendments to §§ 510.305 and 510.315 that became effective May 20, 2017) to performance year 1 subsequent reconciliation calculations. Several commenters favored this approach because they believed it was unlikely for a hospital's quality category to decrease between the initial and subsequent reconciliation. A commenter favored applying the EPM final quality specifications to performance year 1 subsequent reconciliation calculations because they believed applying more generous criteria for earning quality improvement points and using a more appropriate national peer group as the reference for determining performance would result in higher composite quality scores. The commenter stated that these higher composite quality scores would allow more CJR participant hospitals to be eligible for reconciliation payments or to owe smaller repayments and would preserve the ability for high-performing hospitals to earn reconciliation payments that more accurately reflect their performance and investments in the model. The commenter noted that transitioning to the revised composite quality score methodology between the performance year 1 initial and subsequent reconciliation calculations may increase the differences between the results of the two calculations than would otherwise have occurred during subsequent reconciliation due to the anticipated longer claims run out, accounting for model overlap, and post-episode spending adjustments. They stated that the difference would vary by hospital, and could be positive or negative. The commenter clarified that the impact of any larger downward adjustments, however, should occur in performance year 1, when hospitals are not responsible for repayments to CMS if their costs exceed their quality-adjusted target price. Finally, the commenter stated that delaying implementation of the EPM final quality specifications until performance year 2 initial reconciliation calculations would increase CJR operational complexity and complicate evaluation of CJR model results. The commenter urged CMS to

share results from the performance year 1 subsequent reconciliation with participant hospitals as early as feasible in 2018 to minimize uncertainty for hospitals, should a downward adjustment occur.

Response: We appreciate the feedback we received from commenters on the benefits of applying the quality specifications as established in the EPM final rule to performance year 1 subsequent reconciliation calculations, and we thank the commenters for their support of our proposed policy. We agree there are benefits to applying the EPM final rule quality specifications to performance year 1 subsequent reconciliation calculations instead of delaying use of the amended specifications until initial reconciliation for performance year 2. These benefits include reducing the complexity of future evaluation of the model and preventing possibly disadvantaging participants whose composite quality scores would be higher as a result of applying the amended specifications.

Comment: Several commenters opposed our proposal to apply the quality specifications established in the EPM final rule to performance year 1 subsequent reconciliation calculations. A commenter stated that a hospital's payment should not be adjusted for performance year 1 as a result of administrative issues, such as the delay of the effective date for the EPM final rule, which occurred between the initial reconciliation and the subsequent reconciliation for performance year 1.

Response: We appreciate the commenters' concerns regarding possible downward adjustments to the performance year 1 payment amounts that would require repayment recoupment. We intended for the refinements to the CJR model quality measures and composite quality score methodology finalized in the EPM final rule (82 FR 524 through 526) to be effective before the CJR model's performance year 1 initial reconciliation. We acknowledge that the delayed effective date for the EPM final rule has caused frustration, and we acknowledge that a downward adjustment requiring payment recoupment would be burdensome for participant hospitals.

For these reasons, we sought comment on whether using an alternative approach, such as applying the quality composite score methodology from the CJR model final rule to the performance year 1 subsequent reconciliation, would ensure better consistency for analyses across performance years. Commenters generally supported our proposal to apply the quality specifications as established in the EPM final rule. Furthermore, we believe that the benefits to hospitals of applying the quality specifications finalized in the EPM final rule to performance year 1 subsequent reconciliation justify finalizing our proposal. This approach ensures that reconciliation calculations for subsequent performance years will be calculated using the same methodology, eliminating the need for a the development of a crosswalk approach for reconciling differences in composite quality scores across performance years and reducing the impact on future model evaluation efforts.

Comment: Several commenters provided out-of-scope public comments that suggested changes to the composite quality score methodology, the choice of quality measures in the EPM and CJR models, and the patient reported outcomes (PRO) data submission. Several commenters believed the revised composite quality score methodology was not in the best interest of model success, and CMS was inaccurate in stating that the changes to the composite quality score would result in a higher composite quality score for some participant hospitals. Several commenters suggested we include, replace, or drop some or all of the finalized quality measures. Finally, a commenter stated that CMS did not provide sufficient supporting rationale for determinations regarding patient-reported outcomes (PRO) data submission, nor did CMS provide clear information on which patients were eligible for PRO data collection. This commenter requested that CMS provide hospitals with lists of PRO-eligible patients on a regular basis.

Response: We consider these public comments to be outside of the scope of the August 17, 2017 proposed rule. Therefore, we are not addressing them in this final rule and interim final rule with comment period. We may consider these public comments in future rulemaking. We do note that a number of resource guides on the PRO data collection process and eligible patients is available to CJR participant hospitals on the CJR Connect site.

Summary of Final Decisions: We are finalizing our proposal to apply the quality specifications as established in the EPM final rule (that is, the amendments to §§ 510.305 and § 510.315 that became effective May 20, 2017) to performance year 1 subsequent reconciliation calculations.

H. Clarifying and Technical Changes Regarding the Use of the CMS Price (Payment) Standardization Detailed Methodology

Based on questions we received from participant hospitals during the performance year 1 reconciliation process, we proposed to make two technical changes to the CJR model regulations to clarify the use of the CMS Price (Payment) Standardization Detailed Methodology, posted on the QualityNet Web site at *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350,* in the calculation of target prices and actual episode spending. This pricing standardization approach was the same as that used for the Hospital Value-Based Purchasing Program's (HVBP) Medicare spending per beneficiary metric. In section III.C.3.a. of the CJR model final rule (80 FR 73331 through 73333), we finalized how we would operationalize the exclusion of the various special payment provisions in calculating CJR model episode expenditures, both historical episode spending and performance year episode spending, by relying upon the CMS Price (Payment) Standardization Detailed Methodology with modifications. However, we did not clearly articulate the finalized policy in the regulations at 42 CFR part 510. Thus, we proposed the following technical changes to bring the regulatory text into conformity with our intended policy and to reduce potential stakeholder uncertainty about how the price (payment) standardization methodology is used. We proposed to insert ''standardized'' into the definition of actual episode payment in § 510.2, and insert ''with certain modifications'' into § 510.300(b)(6) to account for the modifications we must make to the standardization methodology to ensure all pricing calculations are consistent with our finalized policies.

Comment: We received no comments on our proposal.

Response: We are finalizing our proposal to insert ''standardized'' into the definition of actual episode payment in § 510.2, and insert ''with certain modifications'' into § 510.300(b)(6).

I. Public Comments on Removal of Total Knee Arthroplasty (TKA) From the Inpatient-Only (IPO) List and on the Need for a Disaster Policy for Affected CJR Episodes

1. Pricing Implications of the Removal of TKA From the IPO List

In the CY 2017 Outpatient Prospective Payment System (OPPS) Proposed Rule

(81 FR 45679 through 45681) we sought comment on the potential removal of TKA from the IPO list from interested parties, although we did not make any proposals regarding the issue. We specifically requested input on potential changes to the BPCI initiative and CJR model if we should make such a policy change in the future. In the CY 2018 Outpatient Prospective Payment System (OPPS) Proposed Rule (82 FR 33558), we proposed to remove total knee arthroplasty from the IPO list. We refer readers to that proposed rule for more details regarding the proposal.

Comment: Numerous commenters requested that, should we finalize the proposal to remove TKA from the IPO list, we also finalize a policy to modify the CJR pricing methodology. Commenters stated that if TKA is removed from the IPO list, the CJR target prices will no longer accurately reflect spending for the inpatient population, given that the historical time period used to set prices included all Medicare TKA cases under MS–DRGs 469 and 470, including those that could be performed on an outpatient basis (and are presumably less costly) if TKA is removed from the IPO list. Commenters were concerned that if Medicare begins to pay for TKA in outpatient settings and does not make adjustments to CJR prices, the case mix under the model (that is, beneficiaries in CJR episodes) will include only more costly and higher-acuity cases that are not appropriate for outpatient settings. Thus, LEJR procedures furnished in inpatient settings (and included in CJR episodes) will be more costly than those in outpatient settings, negatively affecting CJR hospitals' potential to financially succeed under the model. Commenters noted that without a pricing adjustment, CJR participant hospitals could have a hard time meeting spending targets if many lower-cost cases move to the outpatient setting. Commenters suggested a variety of solutions, including: Setting a separate target price for outpatient TKA cases and including them in CJR; various methodologies to estimate the removal of outpatient cases from the baseline period when setting target prices; and robust risk adjustment. A commenter suggested we test the removal of TKA from the IPO list as part of our bundled payment models before implementing a change on a national basis. Other commenters stated that hospitals eligible for a voluntary participation election in January 2018 cannot make a participation decision without knowing how CMS will modify the CJR pricing methodology to ensure participant hospitals are not negatively affected by the removal of TKA from the IPO list.

Response: We thank the commenters for their feedback and thoughtful suggestions on ways we could refine the CJR pricing methodology to ensure our decision to remove TKA from the IPO list would not harm hospitals. We refer readers to the 2018 OPPS Final Rule (82 FR 52356) which discusses our finalized policy to remove TKA from the IPO list. Because we did not make a proposal regarding changes to the CJR payment methodology and because there is no clinical experience or claims data yet available for analysis on the potential impacts of this policy change on the CJR target pricing methodology, we will consider all comments and address this issue through future rulemaking, as appropriate.

2. Need for a Policy To Address the Recent Hurricanes and Other Natural Disasters

In late August and September 2017 several hurricanes created significant damage to multiple states and in late September 2017, severe wildfires wreaked havoc on many counties in California.

Comment: Several commenters requested that CMS recognize the unique challenges faced by CJR participant hospitals during the recent natural disasters that have occurred in or near several of the CJR MSAs. Commenters noted that beneficiaries in disaster areas may have required unplanned or extensive healthcare services as a result of evacuation or other emergency situations. Commenters were also concerned that hospitals in the disaster areas would not be able to complete their quality reporting requirements. Commenters stated that CJR participant hospitals should not be held financially accountable for such spending that is beyond their control. Commenters suggested that CMS offer a waiver of the participation requirement or another mechanism to ensure that hospitals are not held accountable for circumstances beyond their control due to natural disasters.

Response: We thank the commenters for their suggestions. We understand that some participant hospitals in the CJR model have been impacted by recent natural disasters and that there is a clear need for a policy in CJR to address expenditures outside the control of hospitals located in areas experiencing extreme and uncontrollable circumstances.

III. Provisions of the Interim Final Rule With Comment Regarding Significant Hardship Due to Extreme and Uncontrollable Circumstances in the CJR Model

A. Overview and Background

This interim final rule with comment period is being issued in conjunction with this final rule to address the need for a policy that would apply for performance year 2 (and, when finalized, that would also apply for the future performance years 3 through 5 of the CJR model) providing some flexibility in determining episode spending for CJR participant hospitals located in areas impacted by extreme and uncontrollable circumstances. This interim final rule with comment period most notably addresses Hurricane Harvey, Hurricane Irma, Hurricane Nate, and the California wildfires of August, September, and October 2017 but could also include other similar events that occur within a given performance year, including performance year 2, if those events meet the requirements we are setting forth in this policy in this interim final rule with comment. While Hurricane Maria, which also occurred in the same time frame, had and, as of the writing of this rule, continues to have a significant and crippling effect on Puerto Rico and the U.S. Virgin Islands, Hurricane Maria is not part of this particular interim final rule with comment as the CJR model is not in operation in the areas impacted by Hurricane Maria, and, therefore there are no CJR participant hospitals that have been impacted by Hurricane Maria. Hurricane Harvey, Hurricane Irma, Hurricane Nate, and the California wildfires affected large regions of the United States where the CJR model operates, leading to widespread destruction of infrastructure that impacted residents' ability to continue normal functions afterwards.

At least 101 CJR participant hospitals are located in the areas affected by Hurricane Irma and Hurricane Harvey, at least 22 CJR participant hospitals are located in areas impacted by the California wildfires and approximately 12 are in the areas affected by Hurricane Nate. Based on a review of news articles focusing on the hurricanes, at least 35 hospitals evacuated for Hurricane Irma [1] and several hospitals evacuated at least partially for Hurricane Harvey.[2] In

[1] Irma forces at least 35 hospitals to evacuate patients. Here's a rundown. September 9, 2017. *https://www.statnews.com/2017/09/09/irma-hospital-evacuations-rundown/.* Accessed November 21, 2017.

[2] After Harvey Hit, a Texas Hospital Decided to Evacuate. Here's How Patients Got Out. September

Florida, at least two CJR participant hospitals in Miami, (Anne Bates Leach Eye Hospital and University of Miami Hospital) and one CJR participant hospital in Miami Beach—Mount Sinai Medical Center—had to close because of Hurricane Irma.[3] Tampa General Hospital, a CJR participant hospital in Tampa, evacuated all patients except for those too ill to move.[4] In response to Hurricane Irma, on September 9, 2017, Tampa Community Hospital, CJR participant hospital, suspended all services and evacuated all patients to two other CJR participant hospitals, Brandon Regional Hospital and Medical Center of Trinity.[5] In Texas, Baptist Beaumont Hospital, a CJR participant hospital in Beaumont, Texas, had to shut down and evacuate on August 31, 2017.[6] On the same day, Christus Southeast Texas St. Elizabeth, another CJR participant hospital in Beaumont, Texas, left only the emergency and trauma center of the hospital open in order to ensure they had enough water for the patients still at the hospital.[6] Patients seeking care at the Medical Center of Southeast Texas, a CJR participant hospital in Port Arthur, Texas, had to be taken by dump truck through the submerged hospital parking lot to the perimeter of the property, where a boat would take them to the hospital.[6] An additional review of news related to California wildfires also shows that the fires caused various hospitals to evacuate patients.[7] On November 16, 2017, five counties in Alabama were declared as major disaster areas due to the destruction of structures, piers, roads and bridges caused by Hurricane Nate.[3] Although we do not yet have enough data to evaluate these events' specific effects on CJR episodes, we anticipate that at least some CJR participant hospitals may have experienced episode cost escalation as a result of hurricane or fire damage and subsequent emergency evacuations.

Under § 510.305(e), as of performance year 2, CJR participant hospitals who have episode costs as calculated under § 510.305(e)(1)(iii) (for example, episode costs that exceed the target price for the performance year) will owe CMS 5 percent of the loss. While the intent of this policy is to incentivize providers to control costs while managing and improving the quality of CJR patient care, we note that in extreme and uncontrollable circumstances, prudent patient care management may involve potentially expensive air ambulance transport or prolonged inpatient stays when other alternatives are not practical due, for example, to state and local mandatory evacuation orders or compromised infrastructure. In addition to the news reports of disaster conditions that impacted several CJR participant hospitals, a number of research studies on natural disasters and rushed evacuations for hospitals support our assumption that costs can rise during disaster situations.[4]

Currently, CJR regulations at § 510.210 do not allow cancellation of episodes for extreme and uncontrollable circumstances. The CJR regulations at § 510.305 also do not permit an adjustment to account for episode spending that may have escalated significantly due to events driven by extreme and uncontrollable circumstances.

B. Identifying Participant Hospitals Affected by Extreme and Uncontrollable Circumstances

For purposes of developing a policy to identify hospitals affected by extreme and uncontrollable circumstances, we consulted section 1135 of the Social Security Act, where the Secretary may temporarily waive or modify certain Medicare requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods and that providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). The Secretary has invoked this authority in response to significant natural disasters such as Hurricane Katrina in 2005 and Superstorm Sandy in 2012. Though the 1135 waiver authority enables us to take actions that give healthcare providers and suppliers greater flexibility, it does not allow for payment adjustment for participant hospitals in the CJR model. However, the extreme and uncontrollable circumstance policy should only apply when a disaster is widespread and extreme. A section 1135 waiver identifies the ''emergency area'' and ''emergency period,'' as defined in section 1135(g) of the Social Security Act, for which waivers are available. We believe it is appropriate to establish an extreme and uncontrollable circumstance policy that applies only when and where the magnitude of the event calls for the use of special waiver authority to help providers respond to the emergency and continue providing care.

The extreme and uncontrollable circumstance policy also should be tailored to the specific areas experiencing the extreme and uncontrollable circumstance. Section 1135 waivers typically are authorized for a geographic area that may encompass a greater region than is directly and immediately affected by the relevant emergency. For purposes of this policy, a narrower geographic scope than the full emergency area (as that term is defined in section 1135(g) of the Act)[5] would ensure that the payment policy adjustment is focused on the specific areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and is not applied to areas sustaining little or no adverse effects.

To narrow the scope of this policy to ensure it is applied to those providers most likely to have experienced the greatest adverse effects, we would therefore also require that the area be declared as a major disaster area under the Stafford Act, which serves as a condition precedent for the Secretary's exercise of the 1135 waiver authority. Once an area is declared as a major disaster area under the Stafford Act, the specific counties, municipalities, parishes, territories, and tribunals that are part of the major disaster area are identified and can be located on Federal Emergency Management Agency

6, 2017. *https://www.nytimes.com/2017/09/06/us/texas-hospital-evacuation.html.* Accessed November 21, 2017.

[3] Hurricane Irma causes 36 Florida hospitals to close. September 12, 2017. *https://www.healthdatamanagement.com/news/hurricane-irma-causes-36-florida-hospitals-to-close.* Accessed November 22, 2017.

[4] At Tampa Hospital in Evacuation Zone, 800 Patients and Staff Ride Out Hurricane Irma. September 10, 2017. *https://weather.com/storms/hurricane/news/hurricane-irma-tampa-hospital-evacuation-zone.* Accessed November 22, 2017.

[5] Tampa Community Hospital has suspended all services and has evacuated patients. September 9, 2017. *https://tampacommunityhospital.com/about/newsroom/tampa-community-hospital-has-suspended-all-services-and-has-evacuated-patients.* Accessed November 22, 2017.

[3] *http://www.al.com/news/mobile/index.ssf/2017/11/trump_declares_major_disaster.html.*

[4] Tia Powell, Dan Hanfling, Lawrence O. Gostin. Emergency Preparedness and Public Health: The Lessons of Hurricane Sandy. *JAMA.* 2012;308(24):2569–2570. doi:10.1001/jama.2012.108940; Christine S. Cocanour, Steven J. Allen, Janine Mazabob, John W. Sparks, Craig P. Fischer, Juanita Romans, Kevin P. Lally. Lessons Learned From the Evacuation of an Urban Teaching Hospital. *Arch Surg.*2002;137(10):1141–1145. doi:10.1001/archsurg.137.10.1141.

[5] (g) DEFINITIONS.—For purposes of this section: (1) EMERGENCY AREA; EMERGENCY PERIOD.—An ''emergency area'' is a geographical area in which, and an ''emergency period'' is the period during which, there exists—(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act[102] or the Robert T. Stafford Disaster Relief and Emergency Assistance Act[103]; and (B) a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

(FEMA) Web site at *www.FEMA.gov/disasters.* For this policy, only major disaster declarations under the Stafford Act will be used to identify the specific counties, municipalities, parishes, territories, and tribunals where the extreme and uncontrollable circumstance took place. Using the major disaster declaration as a requirement for the extreme and uncontrollable event policy also ensures that the policy would apply only when the event is extreme, meriting the use of special authority, and targeting the specific area affected by the extreme and uncontrollable circumstance. To note, we are not including emergency declarations under the Stafford Act or national emergency declarations under the National Emergencies Act in this policy, even if such a declaration serves as a basis for the Secretary's invoking the 1135 waiver authority. This is because we believe it is appropriate for our extreme and uncontrollable circumstance policy to apply only in the narrow circumstance where the circumstance constitutes a major disaster, which are more catastrophic in nature and tend to have significant impacts to infrastructure, rather than the broader grounds for which an emergency could be declared.

In establishing a policy to define extreme and uncontrollable circumstances for the CJR model, we identify an area as having experienced 'extreme and uncontrollable circumstances,' if it is within an ''emergency area'' and ''emergency period'' as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act that served as a condition precedent for the Secretary's exercise of the 1135 waiver authority.

We believe Hurricanes Harvey, Irma, and Nate and the recent California wildfires trigger the automatic extreme and uncontrollable circumstance policy we are adopting in this interim final rule with comment period. For the performance year 2 reconciliation that will be conducted beginning in March of 2018, this extreme and uncontrollable circumstance policy will apply to those CJR participant hospitals whose CCN has a primary address located in a state, U.S. territory, or tribal government that is within an ''emergency area'' and ''emergency period,'' as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act and that is designated in a major disaster declaration under the Stafford Act that served as a condition precedent for the Secretary's exercise of the 1135 waiver authority. The states and territories for which section 1135 waivers were issued in response to Hurricanes Harvey, Irma, Nate and the California wildfires are Alabama, California, Florida, Georgia, South Carolina, Texas, Louisiana, Mississippi. Section 1135 waivers also were issued for Puerto Rico and the Virgin Islands as a result of Hurricane Maria, but there are no CJR participant hospitals with CCNs with a primary address in either of these areas. To view the 1135 waiver documents and for additional information on section 1135 waivers see: *https://www.cms.gov/About-CMS/Agency-Information/Emergency/.* The major disaster declarations are located on FEMA Web site at *https://www.fema.gov/disasters.* When locating the counties, municipalities, parishes, tribunals, and territories for the major disaster declaration, FEMA designates these locations as 'designated areas' for that specific state, or tribunal. All counties, municipalities, parishes, tribunals, and territories identified as designated areas on the disaster declaration are included.

The counties, parishes, and tribal governments that have met the criteria for the CJR policy on extreme and uncontrollable events in performance year 2 are: [6]

- The following counties in Alabama: Autauga, Baldwin, Choctaw, Clarke, Dallas, Macon, Mobile, and Washington.[7]

The following counties in California: Butte; Lake; Mendocino; Napa; Nevada Orange; Sonoma; and Yuba.[8]

- All 67 counties [9] and Big Cypress Indian Reservation, Brighton Indian Reservation, Fort Pierce Indian Reservation, Hollywood Indian Reservation, Immokalee Indian Reservation, Tampa Reservation in Florida.[10]
- All 159 counties in Georgia.[11]
- All 46 counties, and the Catawba Indian Reservation in South Carolina.[12]
- The following counties in Texas: Aransas; Austin; Bastrop; Bee; Bexar; Brazoria; Calhoun; Chambers; Colorado; Dallas; Dewitt; Fayette; Fort Bend; Galveston; Goliad; Gonzales; Hardin; Harris; Jackson; Jasper; Jefferson; Karnes; Kleberg; Lavaca; Lee; Liberty; Matagorda; Montgomery; Newton; Nueces; Orange; Polk; Refugio; Sabine; San Jacinto; San Patricio; Tarrant; Travis; Tyler; Victoria; Walker; Waller; and Wharton.[13]
- The following parishes in Louisiana: Acadia; Allen; Assumption; Beauregard; Calcasieu; Cameron; De Soto; Iberia; Jefferson Davis; Lafayette; Lafourche; Natchitoches; Plaquemines; Rapides; Red River; Sabine; St. Charles; St. Mary; Vermilion; and Vernon.[14]

Using these criteria, CMS was able to identify at least 101 CJR participant hospitals located in the areas affected by Hurricanes Harvey and Hurricane Irma, approximately 12 CJR participant hospitals in the areas affected by Hurricane Nate, and at least 22 CJR participant hospitals in areas impacted by the California wildfires. As there are no CJR model areas in Puerto Rico or the U.S. Virgin Islands, we note that no CJR participant hospitals were impacted by Hurricane Maria. CMS will notify providers for whom this extreme and uncontrollable circumstances policy will apply for performance year 2 (and subsequent performance years if and when the policy is invoked) via the initial reconciliation reports CMS delivers to providers upon completion of the reconciliation calculations, which under § 510.305(d) are initiated beginning 2 months after the close of the performance year.

Though the Hurricanes and California wildfires were the driving force for developing the extreme and uncontrollable circumstance policy, this policy is being implemented for the duration of the CJR model, and we are amending the CJR regulations accordingly, as further outlined later.

B. Provisions for Adjusting Episode Spending Due to Extreme and Uncontrollable Circumstances

Without a policy to provide CJR participant hospitals some flexibility in extreme and uncontrollable circumstances, we might inadvertently create an incentive to place cost considerations above patient safety, especially in the later years of the CJR model when the downside risk percentage increases. In considering policy alternatives to help ensure beneficiary protections by mitigating

[6] The Secretary issued Mississippi a waiver under Section 1135 for Hurricane Nate, however the President did not issue a major disaster declaration (An emergency disaster declaration was issued.), so under this policy Mississippi is not included on this list.

[7] *https://www.fema.gov/disaster/4349/designated-areas.*

[8] *https://www.fema.gov/disaster/4344/designated-areas.*

[9] *https://www.fema.gov/disaster/4337/designated-areas.*

[10] *https://www.fema.gov/disaster/4341/designated-areas.*

[11] *https://www.fema.gov/disaster/4338/designated-areas.*

[12] *https://www.fema.gov/disaster/4346/designated-areas.*

[13] *https://www.fema.gov/disaster/4332/designated-areas.*

[14] *https://www.fema.gov/disaster/4345/designated-areas.*

participant hospitals' financial liability for costs resulting from extreme and uncontrollable circumstances, we considered and rejected a blanket cancellation of all episodes occurring during the relevant period. We do not believe that a blanket cancellation would be in either beneficiaries' or CJR participant hospitals' best interests, as it is possible that hospitals can manage costs and earn a reconciliation payment despite these extreme and uncontrollable circumstances.

Furthermore, we would not want CJR participant hospitals to limit case management services for beneficiaries in CJR episodes during extreme and uncontrollable circumstances, when prudent care management could potentially involve using significantly more expensive transport or care settings. Therefore, we determined that capping the actual episode spending at the target amounts for those episodes would be the best way to protect beneficiaries from potential care stinting and hospitals from escalating costs. This will also ensure that those hospitals are still able to earn reconciliation payments on those eligible episodes where the disaster did not have a noticeable impact on cost.

In determining the start date of episodes to which this extreme and uncontrollable circumstances policy would apply, we determined that a window of 30 days prior to and including the date that the emergency period (as defined in section 1135(g)) begins should reasonably capture those beneficiaries whose high CJR episode costs could be attributed to extreme and uncontrollable circumstances. We believe this 30-day window is particularly appropriate due to the 90-day CJR model episode length. Including all episodes that begin within 30 days before the date the emergency period begins should enable us to include the majority of beneficiaries still in institutional settings and who are still within the first third of their episodes when the extreme and uncontrollable circumstance arises. We note that the average length of stay for DRG 469 is between 5 and 6 days and the average length of stay for DRG 470 is between 2 and 3 days (see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2018-CMS-1677-FR-Table-5.zip*).

Under § 510.300(a)(1), we differentiated fracture and non-fracture CJR episodes and pricing, noting that lower extremity joint replacement procedures performed as a result of a hip fracture are typically emergent procedures. Fracture episodes typically occur for beneficiaries with more complex health issues and can involve higher episode spending. We do not expect a high volume of CJR non-fracture episodes to be initiated once extreme and uncontrollable circumstances arise, given that it is not prudent to conduct non-fracture major joint replacement surgeries, which generally are elective and non-emergent, until conditions stabilize and infrastructure is reasonably restored. Therefore, for non-fracture episodes, this extreme and uncontrollable circumstances policy will apply only to dates of admission to anchor hospitalization that occur between 30 days before and up to the date on which the emergency period (as defined in section 1135(g)) begins. We believe this policy empowers hospitals to decide whether they can safely and appropriately perform non-fracture THA and TKA procedures after the commencement of the emergency period and whether or not performing these procedures will subject their organization to undue financial risk resulting from increased costs that are beyond the organization's control.

However, for CJR fracture episodes, the extreme and uncontrollable circumstances policy will apply to dates of admission to the anchor hospitalization that occur within 30 days before, on, or up to 30 days after the date the emergency period (as defined in section 1135(g)) begins. We recognize that fracture cases in CJR are often emergent and unplanned, and it may not be prudent to postpone major joint surgical procedures in many of those CJR fracture cases. Therefore, fracture episodes with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins are subject to this extreme and uncontrollable circumstances policy. We believe that this 60-day window should ensure that hospitals caring for CJR fracture patients during extreme and uncontrollable circumstances are adequately protected from episode costs beyond their control.

For performance years 2 through 5, for participant hospitals that are located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135, and in a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, the following conditions apply. For a non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g)) begins, actual episode payments are capped at the target price determined for that episode under § 510.300. For a fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g)) begins, actual episode payments are capped at the target price determined for that episode under § 510.300.

We are codifying this new extreme and uncontrollable circumstance policy at § 510.305(k). We seek comment on potential modifications refinements we might make to this policy for future performance year reconciliations after performance year 2.

D. Waiver of Proposed Rulemaking for Provisions Related to Extreme and Uncontrollable Circumstances

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide notice of the proposed rule in the **Federal Register** with no less than 60 days for public comment. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice-and-comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice-and-comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to the impact of Hurricanes Harvey, Irma, and Nate and the California wildfires as described in section A. of this interim final rule with comment period. Based on the size and scale of the destruction and displacement caused by these natural disasters in the regions identified, and the news reports regarding specific impacts to hospitals that are participating in the CJR model discussed in section A of this interim final rule with comment, we believe it is likely that some CJR episodes at participant hospitals have been significantly and adversely affected by these events. As discussed in detail in section A of this interim final rule with comment, due to extreme flooding or infrastructure destruction where many major and minor roads became impassable and homes and/or institutions were flooded and rendered

inhabitable, it is possible that some beneficiaries may have required air ambulance transport or extended institutional stays in inpatient or post-acute care settings; these necessary services may drive actual episode costs well beyond the target prices.

Furthermore, we received several requests for CMS to provide concessions for the unique challenges faced by CJR hospitals during the recent natural disasters. Commenters on the proposed rule noted that beneficiaries in disaster areas may have required unplanned or extensive healthcare services as a result of evacuation or other emergency situations and stated that CJR participant hospitals should not be held financially accountable for such spending that is beyond their control. They suggested that CMS offer a waiver of the participation requirement or another mechanism to ensure that hospitals are not held accountable for circumstances beyond their control due to natural disasters.

Because the recent disasters impacted CJR participant hospitals during performance year 2 and will therefore flow into the payment reconciliation calculations in March 2018, potentially having a negative impact on providers unless an extreme and uncontrollable events policy is established immediately, we believe it is in the public interest to adopt these final policies. These policies will provide relief to impacted CJR participant hospitals and ensure they do not incur financial liability for costs outside their control. Without the immediate establishment of a policy providing additional flexibilities to CJR participant hospitals in extreme and uncontrollable circumstances, we could inadvertently incentivize patient care stinting as CJR participant hospitals contend with evacuation costs or potential longer inpatient stays during disasters. In particular, CJR hospitals may experience unintentional negative incentives as compared to other, non-CJR hospitals because their actual spending is compared to target prices, and they have downside risk responsibility for excess spending beyond their target prices. Without flexibilities provided, CJR hospitals in disaster areas may experience financial strain which could incentivize behaviors that could compromise the quality of care provided. Providing CJR participant hospitals with additional concessions in extreme and uncontrollable circumstances will strengthen beneficiary protections, which are integral to the model's goal of improving care quality.

For the reasons discussed previously, we believe that it would be contrary to the public interest to undergo notice-and-comment procedures before finalizing the policies described for CJR participant hospitals that have been affected by extreme and uncontrollable events during performance year 2 of the model. Performance year 2 began on January 1, 2017 and concludes on December 31, 2017. With this interim final rule with comment period, it is our intention to reduce burden on and protect CJR participant hospitals and beneficiaries impacted by extreme and uncontrollable events. This extreme and uncontrollable circumstances policy will take effective with the publication of this final rule and interim final rule with comment and will be used during the reconciliation process for performance year 2 episodes that will occur beginning in March of 2018. We believe that an interim final rule with comment period minimizes hospitals' financial burden and avoids patient harm due to extenuating circumstances, efforts which would otherwise be protracted and become effective after the conclusion of performance year 2 if done through the notice-and-comment rulemaking process. Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 1871(b)(2)(C) of the Act and section 553(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

E. Collection of Information Requirements Related to Extreme and Uncontrollable Circumstances

As stated in section 1115A(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 and interim final rule with comment period need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated cost burden associated with the information collection requirements in the Regulatory Impact Analysis section of this final rule and interim final rule with comment period.

F. Impacts Related to Extreme and Uncontrollable Circumstances

In order to estimate the impacts resulting from this interim final rule with comment period, we utilized 2016 CJR episode level data to approximate the impact to projected CJR model savings resulting from the extreme and uncontrollable circumstance policy we are implementing in this interim final rule with comment period. Specifically, we first identified the CJR participant hospitals located in Alabama, California, Florida, Georgia, South Carolina, Mississippi, Texas and Louisiana (those states for which 1135 waivers were issued) that were also located in the counties listed in section III.A. of this interim final rule with comment period and listed on *www.FEMA.gov/disasters* as having a major disaster declaration. To approximate the date of the emergency, we used the date of the disasters as listed on the FEMA Web site from 2017 (resetting the year to 2016 to align with the claim dates of service) and selected all CJR episodes for these providers that initiated in the month preceding (that is, 30 days prior) the date of the disaster. Date of disaster declaration dates were matched to the CJR participant hospitals based on the hospitals' state addresses.

For non-fracture episodes, we capped the actual episode payment at the target price determined for that episode if the date of admission to the anchor hospitalization is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins. For fracture episodes, we capped the actual episode payment at the target price determined for that episode if the date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins. Our analyses indicate that the impact of capping the actual episode payments at the episode target prices based on the 2017 extreme and uncontrollable events policy could result in a decrease to the CJR model estimated savings ranging between $1.5 to $5.0 million for performance year 2. We note that the projected impact was mitigated by the 5 percent stop-loss/stop-gain levels applicable to performance year 2 and add that if these disasters had occurred in a future performance year with higher stop-loss/stop-gain levels then we would expect the projected impact to increase. These savings estimates do not assume any change in spending or volume due to these extreme and uncontrollable circumstances, neither before nor after the date of the disaster as listed on the FEMA Web site.

We utilized 2016 CJR model episode data assuming that it presented the best available proxy for estimating impacts to projected CJR model savings resulting from 2017 disasters. We modeled impact to savings projections using 2016 data during the same months in which

the 2017 disasters occurred, for hospitals impacted by the disasters. We note that due to lack of available actual claims data due to timing, we could not utilize actual 2017 performance data to estimate impacts from this interim final rule with comment period.

Our estimates resulted from modeling which utilized all CJR model episode data for impacted hospitals in Alabama, Georgia, South Carolina, Louisiana, and California for the month of October, 2016 and CJR model fracture episodes only for impacted hospitals in Alabama, Georgia, South Carolina, Louisiana, and California for the month of November, 2016. We also utilized all CJR episode data for impacted hospitals in Texas and Florida during the month of September, 2016 and CJR model fracture episodes only for impacted hospitals in Texas and Florida for the month of October 2016. To model estimated impacts to savings projections resulting from this interim final rule with comment period, we recalculated NPRA based on the aforementioned policies.

While we acknowledge that our estimates related to impacts resulting from this interim final rule with comment period may under- or over-estimate actual impacts resulting from the policies, we believe our assumptions are well-aligned with our other impact projections in this final rule and appropriately reflect our estimates of the impacts resulting from these policies.

IV. Collection of Information Requirements

As stated in section 1115A(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 and interim final rule with comment period need not be reviewed by the Office of Management and Budget. However, we have summarized the anticipated cost burden associated with the information collection requirements in the Regulatory Impact Analysis section of this final rule and interim final rule with comment period.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule and interim final rule with comment period 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)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule cancels the EPMs and the CR Incentive Payment Model in advance of their start date and revises the design of the CJR model; these provisions impact a subset of hospitals under the IPPS. Therefore, it would have a relatively small economic impact; as a result, this final rule does not reach the $100 million threshold and thus is neither an ''economically significant'' rule under E.O. 12866, nor a ''major rule'' under the Congressional Review Act.

B. Statement of Need

As discussed previously, review and reevaluation of policies and programs, as well as revised rulemaking, are within an agency's discretion, especially after a change in administration occurs. After review and reevaluation of the CJR model final rule, the EPM final rule and the public comments we received in response to the March 21, 2017 IFC, in addition to other considerations, we have determined that it is necessary to rescind the regulations at 42 CFR part 512 and to reduce the scope of the CJR model for the following reasons. We believe that reducing the number of hospitals required to participate in the CJR model will allow us to continue to evaluate the effects of such a model while limiting the geographic reach of our current mandatory models. Additionally, we believe that canceling the EPMs and CR Incentive Payment Model, as well as altering the scope of the CJR model, offers CMS maximum flexibility to design alternative episode-based models and make potential improvements to these models as suggested by stakeholders, while still allowing us to test and evaluate the impact of the CJR model on the quality of care and expenditures.

This final rule and interim final rule with comment period is also necessary to improve the CJR model for performance years 3, 4, and 5. We are implementing a few technical refinements and clarifications for certain payment, reconciliation and quality provisions, and changing the criteria for the Affiliated Practitioner List to broaden the CJR Advanced APM track to additional eligible clinicians. We believe these refinements will address operational issues identified since the start of the CJR model.

C. Anticipated Effects

In section III. of this final rule and interim final rule with comment period, we discuss the policies we are finalizing to amend the regulations governing the CJR model. We present the following estimated overall impact of the proposed changes to the CJR model. Table 6 summarizes the estimated impact for the CJR model for the last 3 years of the model. The modeling methodology for provider performance and participation is consistent with the methodology used in modeling the CJR impacts in the EPM final rule (82 FR 596). However, we updated our analysis to include an opt-in option for hospitals in 33 of the 67 MSAs selected for participation in the CJR model (all but 4 of these MSAs are from the lower cost groups), while maintaining mandatory participation for the remaining 34 MSAs (all of which are from the higher cost groups), and allowing for the exclusion of low-volume and rural hospitals in these 34 MSAs from mandatory participation and allowing them to choose voluntary participation (opt-in).

We note that we updated the list of excluded rural hospitals between the proposed and final rules as we did not have a complete set of rural hospitals; this final rule now includes in the analysis approximately 23 additional rural hospitals that we anticipate will not opt-in to the CJR model in this final rule. We expect the number of mandatory participating hospitals from year 3 forward to decrease from approximately 700, which is approximately the number of current CJR participant hospitals, to approximately 370. We assumed that if a hospital would exceed its target pricing such that it would incur an obligation of repayment to CMS of 3 percent or more in a given year, that hospital would not elect voluntary participation in the model for the final 3 performance years.

We assumed no low-volume hospitals would participate, noting that including

them in impacts would not have any noticeable effects due to their low claims volume. For purposes of identifying CJR rural hospitals for this impact, we used the 2018 IPPS § 412.103 rural reclassification list and checked the addresses of record for the CJR hospitals to identify any located within the rural RUCA census tracts. The likelihood of voluntary participation linearly increases based on an upper bound of 3 percent bonus, but the modeling assumed that 25 percent of hospitals in the voluntary MSAs would not consider participation so that the likelihood of participation for each hospital was capped at 75 percent; we expected 60 to 80 hospitals to elect voluntary participation in the model. We sought comment on our assumptions about the number of hospitals that would elect voluntary participation in the CJR model.

Due to a lack of available data, we did not account for participant investment in the impact analysis model we used for the proposed rule. However, we noted that we would expect that those who choose to voluntarily participate would have made investments in the CJR model that enable them to perform well and that they would anticipate earning positive reconciliation payments. For those hospitals choosing not to voluntarily participate, we would expect that the cost of any investments they may have made based on their participation in performance years 1 and 2 of the CJR model would be outweighed by the reconciliation payment obligations they would expect to incur if they continued to participate.

The 60 to 80 participants we expect to continue participating in the model through the voluntary election process are not included in our previous estimate of 370 CJR participants in the mandatory MSAs. Thus, in total we expected approximately 430 to 450 participants in the CJR model for the final 3 performance years. The participation parameters were chosen to reflect both the anticipated risk aversion of hospitals, and an expectation that many participants do not remain in an optional model or demonstration when there is an expectation that the hospital would incur an obligation of repayment to CMS. These assumptions reflected the experience with other models and demonstrations. The value of 3 percent may be somewhat larger than the level of repayment at which hospitals would opt-in, but the value was chosen to allow for the uncertainty of expected claims. We noted that the possibility of shifting episodes from CJR model participant hospitals to low-volume or other non-participating hospitals exists and that we did not include any assumptions of this potential behavior in our financial impact modeling. We sought comment on our model assumptions that shifting of episodes will not occur.

The calculations estimated that the CJR model would result in a net Medicare program savings of approximately $189 million over the 3 remaining performance years (2018 through 2020). This represents a reduction in savings of approximately $106 million from the estimated net financial impacts of the CJR model in the EPM final rule (82 FR 603).

Our previous analyses of the CJR model did not explicitly model for utilization changes, such as improvements in the efficiency of service during episodes. However, these behavioral changes would have minimal effect on the Medicare financial impacts. If the actual costs for an episode are below the discounted bundled payment amount, then CMS distributes the difference between these two amounts to the participant hospital, up to a capped amount. Similarly, if actual costs for an episode are above the discounted bundled payment amount, then the participant hospital pays CMS the difference between these amounts, up to a capped amount. Due to the uncertainty of estimating the impacts of this model, actual results could be higher or lower than this estimate.

TABLE 6—COMPARISON OF INITIAL ESTIMATE OF THE IMPACT ON THE MEDICARE PROGRAM OF THE CJR MODEL WITH REVISED ESTIMATES

[Figures are in $ millions, negative values represent savings]

Year	2018	2019	2020	Total
Initial CJR Estimate	−61	−109	−125	−294
Revised CJR Estimate	−35	−72	−82	−189
Change	26	37	43	106

Note: The initial estimate included the changes to the CJR model finalized in the EPM final rule (82 FR 603). The 2016 and 2017 initial estimate was not impacted by the proposed changes to the CJR model in the August 17, 2017 proposed rule (82 FR 39310 through 39333). The total column reflects 2018 through 2020. Totals do not necessarily equal the sums of rounded components.

The revised impact of EPM and the CR Incentive Payment as a result of ''Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model'' published in the January 3, 2017 **Federal Register** (82 FR 597), estimated an annual cost of $32 million for 2018 and annual savings of $29 million, $36 million, $52 million, and $119 million for years 2019–2022, respectively. Additionally, assuming a zero percent growth in cardiac rehabilitation resulting from the CR Incentive Payment Model (see 82 FR 604 for a discussion of the original cardiac rehabilitation impact where we estimated an impact range between a cost of $29 million to a savings of $32 million over 2017 to 2024; we note we assumed a zero percent growth rate for purposes of the accounting statement in the January 3, 2017 final rule and continue to do so here), we projected annual costs to the Medicare program of $4.8 million, $6.7 million, $7.2 million, $7.6 million, $8.1 million for the years 2018 through 2022, respectively, and projected neither costs nor savings for the years 2023 and 2024. Table 7 summarizes the anticipate changes to the savings and cost estimates resulting from the cancellation of the EPMs and CR Incentive Payment model relative to the previously projected savings estimates. Overall, the change to projected savings and costs resulting from the cancellation of these models totals $170 million, reflecting a reduction in savings for years 2018 through 2022 resulting from cancelation of the EPMs and a reduction in costs for years 2018 through 2022 resulting from the cancelation of the CR Incentive Payment Model.

TABLE 7—COMPARISON OF INIITIAL ESTIMATE OF THE IMPACT ON THE MEDICARE PROGRAM OF THE EPMS AND CR INCENTIVE PAYMENT MODEL WITH REVISED ESTIMATES

[Figures are in $ millions, negative values represent savings]

Year	2018	2019	2020	2021	2022	Total
Previous EPM Estimate	$32	($29)	($36)	($52)	($119)	($204)
Previous CR Incentive Payment Model Estimate	5	7	7	8	8	34
Total Initial Estimate	37	(22)	(29)	(45)	(111)	(170)
Revised Total Estimate	0	0	0	0	0	0
Change	(37)	22	29	45	111	170

Note: Totals do not necessarily equal the sums of rounded components.

Our analysis presented the cost and transfer payment effects of the proposed rule to the best of our ability.

Comment: Several commenters questioned the validity of our proposed estimated reduction in savings of $90 million throughout the remainder of the model due to the proposed changes to the CJR model. The commenter stated that the projected $90 million in reduced savings is only part of the total savings that would result from continuing the CJR model in its original, entirely mandatory, form. This commenter stated that savings will increase due to the CJR model's increased regional pricing component beginning in performance year 4.

Response: We thank the commenters for their input. We acknowledge that our total savings estimates (which we note shifted from $90 million in the proposed rule to $108 million in this final rule and interim final rule with comment period, with $106 million due to final changes to the CJR model as (well as the exclusion of an additional 23 rural hospitals we did not account for in the proposed rule) and an additional $2 million resulting from the impacts of this interim final rule with comment) may prove imperfect. As with all rule and regulation development, CMS utilized standard savings modeling methodology to determine estimates of the effects from this rule. Our current modeling reflects our proposal to alter the existing CJR model for the final three performance years of 2018 through 2020.

Comment: A commenter asserted that the proposed voluntary model structure would allow for ''cherry picking'' of CJR patients by participating hospitals and create selection bias that may alter or interfere with evaluation efforts.

Response: We appreciate the commenter's concern about the proposed voluntary format. We note that the final policy will allow for a one-time opt in for certain hospitals and that these hospitals will be participants in the CJR model should they elect to proceed. Hospitals that elect to voluntarily participate in CJR will be held to the same standards, regulations and programmatic expectations as the hospitals within the mandatory MSAs. Thus, we would not anticipate hospitals electing voluntary participation in CJR to be any more or less likely than hospitals within the mandatory MSAs to engage in concerning behaviors such as care stinting or biased patient selection for surgery. We appreciate the commenter's concern that the proposed model design could impede evaluation efforts and refer readers to discussion of the impact on the evaluation in section II.A of this final rule and interim final rule with comment period.

D. Effects on Beneficiaries

We believe that the cancellation of the EPMs and CR Incentive Payment Model will not affect beneficiaries' freedom of choice to obtain healthcare services from any individual or organization qualified to participate in the Medicare program, including hospitals that are making care improvements within their communities. Although these models seek to incentivize care redesign and collaboration throughout the inpatient and post-acute care spectrum, the models have not yet begun. As the current baseline assumes these models will become effective on January 1, 2018, and that these models will incentivize care improvements that will likely result in an increase in quality of care for beneficiaries, we note that it is possible that the cancellation of these models may cause hospitals that potentially made improvements in care in anticipation of the start of these models to delay or cease these investments, which may result in a reversal of any recent quality improvements. However, we believe the concerns raised by stakeholders and the lack of time to consider design improvements for these models prior to the January 1, 2018 start date outweigh potential reversal of any recent improvements in care potentially made by some hospitals and warrant cancellation of these models at this time while we engage with stakeholders to identify future tests for bundled payments and incentivizing high value care.

We believe that the changes to the CJR model discussed in this final rule and interim final rule with comment period, specifically focusing the model on higher cost MSAs in which participation will continue to be mandatory and allowing low-volume and rural hospitals and all participant hospitals in lower cost MSAs to choose voluntary participation, will maintain the potential benefits of the CJR model for beneficiaries in many areas while providing a substantial number of hospitals with increased flexibility to better focus on priority needs of the beneficiaries they serve. Specifically, low-volume and rural hospitals as well as other hospitals in the 33 voluntary participation MSAs (which are relatively more efficient areas) may elect to participate in the CJR model if they believe that doing so best meets their organization's strategic priorities for serving the beneficiaries in their community. Alternatively, if these hospitals do not believe continued participation in the CJR model will benefit their organizational goals and local patient care priorities, they may elect not to opt-in for the remainder of the model. We believe that beneficiaries in the service areas of the hospitals that will be allowed to choose to participate in the CJR model may have an ongoing benefit from the care redesign investments these hospitals have already made during the first 2 years of the CJR model. Overall, we believe the refinements to the CJR model implemented by this final rule and interim final rule with comment period do not materially alter the potential effects of the model on beneficiaries. However, we acknowledge the possibility that the improved quality of care that was likely to have occurred during performance years 1 and 2 of the CJR model may be curtailed for beneficiaries that receive care at

hospitals that do not elect to continue participation in the CJR model.

Comment: A commenter expressed concern for the unintended consequences on beneficiaries that result from implementation of mandatory models. The commenter stated that a mandatory approach to model implementation will force some hospitals to participate in a model for which they are ill-prepared, potentially limiting beneficiaries' access to care.

Response: We appreciate the commenter's concern about unintended consequences resulting from the CJR model and as such, note that beneficiary protection remains a very high priority as originally specified in the CJR final rule. We will continue to diligently monitor CJR model participant behavior for the potential for any adverse outcomes resulting from model participation.

E. Effects on Small Rural Hospitals

The changes to the CJR model implemented by this final rule and interim final rule with comment period do not substantially alter our previous impacts of the impact on small, geographically rural hospitals specified in either the EPM final rule (82 FR 606) or the CJR model final rule (80 FR 73538) because we continue to believe that few geographically rural hospitals will be included in the CJR model. In addition, allowing all rural hospitals (as defined in § 510.2) that are not otherwise excluded the opportunity to elect to opt-in to the CJR model instead of having a mandatory participation requirement may further reduce the likelihood that rural hospitals will be included in the model. We solicited public comment on our estimates and analysis of the impact of our proposals on small rural hospitals.

Comment: We received no comments regarding the effects of these policies on small rural hospitals.

F. 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 estimated 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/smallbusiness-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 and interim final rule with comment period 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, skilled nursing facilities, 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 and interim final rule with comment period discusses aspects of episode payment models that may or would affect them, we have no reason to assume that these effects would reach the threshold level of 3 percent of revenues used by HHS to identify what are likely to be ''significant'' impacts. 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. Hospitals currently experience frequent changes to payment (for example, as both hospital affiliations and preferred provider networks change) that may impact revenue, and we have no reason to assume that this will change significantly under the changes implemented by this final rule and interim final rule with comment period.

Accordingly, we have determined that this final rule and interim final rule with comment period 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 the proposed rule on those small entities.

Comment: We did not receive comments regarding this section.

G. Effects of Information Collection

The changes implemented by this final rule and interim final rule with comment period will have a minimal additional burden of information collection for CJR model participant hospitals. The two areas which this final rule and interim final rule with comment period may increase participant burden include providing clinician engagement lists and submitting opt-in documentation (for eligible hospitals who choose to opt-in to the CJR model).

Clinician engagement list submission for the CJR model will require that participants submit on a no more than quarterly basis a list of physicians, non-physician practitioners, or therapists who are not a CJR model collaborator during the period of the CJR model performance year specified by CMS but who do have a contractual relationship with a CJR model participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the performance year specified by CMS.

For hospitals eligible to opt-in to the CJR model that elect to participate in the model, CMS intends to provide a template that can be completed and submitted prior to the January 31, 2018 submission deadline. As stated previously, we estimate that the number of hospitals that will elect voluntary participation in CJR is 60 to 80. As stated previously, this template would be designed to minimize burden on participants, and the template will capture the information required to effectively opt-in to the model. Using wage information from the Bureau of Labor Statistics for medical and health service managers (Code 11–9111), we assumed a rate of $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*) and estimated that the time to complete the opt-in template would be, on average, approximately 30 minutes per hospital. Thus, total costs associated with completing opt-in templates for all 60 to 80 hospitals projected to elect voluntary participation is expected to range between $3,150 (60 hospitals) and $4,200 (80 hospitals).

We sought comment on our assumptions and information on any costs associated with this work.

Comment: Several commenters stated that the administrative burden resulting from the clinician engagement list requirements, sharing arrangement reporting and beneficiary notification mandates of the CJR model is overwhelming. A commenter added that any reduction in burden that can be achieved would be helpful to hospitals and would enable patient-centered care. Another commenter stated that they have significant concerns about hospitals' ability to maintain accurate clinician engagement lists with start and end dates for each clinician. The commenter noted that this would be particularly challenging for hospitals in California, where they believe alignment with providers is particularly complicated, thus making a list of this type burdensome to maintain.

Response: We appreciate the commenters' concerns over the administrative burden associated with the CJR model as well as the burden

resulting from clinician engagement lists and the concern that maintaining accurate lists will prove particularly difficult for some providers. We acknowledge that the requirement of submitting clinician engagement lists may be burdensome for providers. However, as discussed in section III.F. of the proposed rule, we developed this requirement in response to feedback from stakeholders who expressed a desire to enhance opportunities for those physicians, non-physician practitioners, and therapists without a financial arrangement under the CJR model, but who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM for purposes of the Quality Payment Program.

H. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule and interim final rule with comment period, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the final rule and interim final rule with comment period, we assume that the total number of unique commenters on the July 25, 2016 proposed rule that proposed the EPMs and CR Incentive Payment Model will be the number of reviewers of this final rule and interim final rule with comment period. We received 85 unique comment submissions for this final rule but maintain that the 175 comments received for the July 25, 2016 EPM and CR Incentive Payment Model proposed rule reflects a more conservative estimate of the number of organizations which invested resources in review of this final rule, regardless of whether or not the organization elected to formally submit comments. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule and interim final rule with comment period. It is possible that not all commenters reviewed the precedent rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters on the EPM proposed rule would be a fair estimate of the number of reviewers of this rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. However, for the purposes of our estimate we assume that each reviewer reads approximately 100 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $105.16 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 1.6 hours for the staff to review the proposed rule. For each entity that reviews the rule, the estimated cost is $168.26 (1.6 hours × $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $29,445 ($105.16 × 175 reviewers).

I. 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 2017, that is approximately $148 million. This final rule and interim final rule with comment period does not include any mandate that would result in spending by state, U.S. territories, local or tribal governments, in the aggregate, or by the private sector in the amount of $148 million in any 1 year.

J. Federalism

We do not believe that there is anything in this final rule and interim final rule with comment period that either explicitly or implicitly preempts any state law, and furthermore we do not believe that this final rule and interim final rule with comment period will have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication.

K. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule and interim final rule with comment period is not expected to be subject to the requirements of E.O. 13771 because it is estimated to result in no more than *de minimis* costs.

L. Alternatives Considered

Throughout this final rule and interim final rule with comment period, 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. We considered but did not propose to allow voluntary participation in all of the 67 selected MSAs in the CJR model because the overall estimated CJR model impact would no longer show savings, and would likely result in costs. An entirely voluntary CJR model would likely result in costs due to the assumption that, in aggregate, hospitals that expect to receive a positive reconciliation payment from Medicare would elect to opt-in to the model while hospitals that expect to owe Medicare a reconciliation amount would not likely elect to participate in the model. We also considered but did not propose limiting participation to the proposed 34 mandatory participation MSAs and not allowing voluntary participation in any of the 67 selected MSAs. In the August 17, 2017 proposed rule, we noted that if participation was limited to the proposed 34 mandatory participation MSAs and voluntary participation was not allowed in any MSA, the impact to the overall estimated model savings over the last 3 years of the model would be closer to $30 million than the $90 million estimate presented in section V. of the proposed rule (82 FR 39327 through 39331), because our modeling did not include assumptions about behavioral changes that might lower fee-for-service spending. Since our impact model estimated that 60 to 80 hospitals would choose voluntary participation and that these potential voluntary participants would be expected to earn only positive reconciliation payments under the model, these positive payments to the voluntary participants would offset some of the savings garnered from mandatory participants. However, we did propose to allow voluntary participation in the proposed 33 voluntary participation MSAs and for low-volume and rural hospitals to permit hospitals that have made investments in care redesign and commitments to improvement to continue to participate in the model for the remaining 3 years. We stated that we believed our proposal would benefit a greater number of beneficiaries because a greater number of hospitals would be included in the CJR model.

Instead of proposing to cancel the EPMs and CR Incentive Payment Model, we considered altering the design of these models to allow for voluntary participation but as this would potentially involve restructuring the model design, payment methodologies, financial arrangement provisions and/or quality measures, we did not believe that such alterations would offer providers enough time to prepare for such changes, given the planned

January 1, 2018 start date. In addition, if at a later date we decided to offer these models, or similar models we would not expect to implement them through rulemaking if done on a voluntary basis, but rather would establish them consistent with the manner in which we have implemented other voluntary models.

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 did not receive any comments regarding this section.

M. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*) in Table 8, we have prepared an accounting statement showing the classification of transfers associated with the provisions in this final rule and interim final rule with comment period. The accounting statement is based on estimates provided in this regulatory impact analysis. As described in Table 6, we estimate the changes to the CJR model will continue to result in savings to the federal government of approximately $189 million over the 3 remaining performance years of the model from 2018 to 2020, noting these changes do reduce the original CJR estimated savings by approximately $106 million. As described in section F of the interim final rule with comment in this rule, we anticipate an additional cost due to currently known events between $1.5 and $5 million from the extreme and uncontrollable events policy we are establishing in this interim final rule with comment. We project $2.0 million as a point-estimate for one-time cost associated with the extreme and uncontrollable events policy during performance year 2. The impact over subsequent years will depend on the number of events in CJR regions and the stop-gain and stop-loss limits for that year. In Table 8, the overall annualized change in payments (for all provisions in this final rule and interim final rule with comment period relative to the CJR, EPM and CR models as originally finalized) based on a 7-percent and 3-percent discount rate, results in net federal monetary transfer from the federal government to participant IPPS hospitals of $199.3 million and $239.1 million in 2017 dollars, respectively, over the period of 2018 to 2022. Both of these estimates of the net transfer would increase by $2 million for the one-time cost of the 2017 disaster declarations.

TABLE 8—ACCOUNTING STATEMENT CHANGES TO COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL AND CANCELLATION OF EPISODE PAYMENT MODELS AND CR INCENTIVE PAYMENT MODEL FOR PERFORMANCE YEARS 2018 TO 2022 AND CJR EXTREME AND UNCONTROLLABLE CIRCUMSTANCES POLICY 2017

Category	Estimates	Units		
		Year dollar	Discount rate (%)	Period covered
Costs: *				
Upfront cost of regulation ($million)	0.03	2017	7	–2018 upfront cost.
	0.03	2017	3	–2018 upfront cost.
From Whom to Whom	Incurred by IPPS Hospitals as a result of this final rule.			
Impact of Disaster Declaration in 2017:				
One-time cost of Disaster Declaration	2	2017	7	–2017 one-time cost.
	2	2017	3	–2017 one-time cost.
From Whom to Whom	From the Federal Government to 2017 disaster declaration hospitals.			
Transfers:				
Annualized/Monetized ($million/year)	48.6	2017	7	2018–2022.
	52.2	2017	3	2018–2022.
From Whom To Whom	From the Federal Government to Participating IPPS Hospitals.			

* The cost includes the regulatory familiarization and completing opt-in templates for up to 80 hospitals to join the CJR model.

N. Conclusion

This analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule. As a result of this final rule and interim final rule with comment period, we estimate that the financial impact of the changes to the CJR model will result in a reduction to previously estimated savings by $106 million over the 3 remaining performance years (2018 through 2020) and a financial impact of $2 million reduction in savings estimates for the one-time cost resulting from the impacts of disaster declaration in 2017 although we note that the CJR model will still be estimated to save the Medicare program approximately $189 million over the remaining 3 performance years. We note that the projected $170 million savings we had estimated that the EPMs and CR Incentive Payment Model would generate for the Medicare program will not be realized as this final rule and interim final rule with comment is cancelling those models.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 510

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health facilities, Health professions, 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 set forth below.

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

■ 1. The authority citation for part 510 continues to read as follows:

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

■ 2. Section 510.2 is amended by—
■ a. Revising the definition of ''Actual episode payment'';
■ b. Adding, in alphabetical order, definitions of ''Low-volume hospital'' and ''Mandatory MSA''.
■ c. Revising the definition of ''Participant hospital''; and
■ d. Adding the definition of ''Voluntary MSA''.

The revisions and additions read as follows:

§ 510.2 Definitions.

* * * * *

Actual episode payment means the sum of standardized Medicare claims payments for the 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).

* * * * *

Low-volume hospital means a hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the performance year 1 CJR episode target prices.

* * * * *

Mandatory MSA means an MSA designated by CMS as a mandatory participation MSA in accordance with § 510.105(a).

* * * * *

Participant hospital means one of the following:

(1) During performance years 1 and 2 of the CJR model and the period from January 1, 2018 to January 31, 2018 of performance year 3, a hospital (other than a hospital excepted under § 510.100(b)) with a CCN primary address located in one of the geographic areas selected for participation in the CJR model in accordance with § 510.105.

(2) Beginning February 1, 2018, a hospital (other than a hospital excepted under § 510.100(b)) that is one of the following:

(i) A hospital with a CCN primary address located in a mandatory MSA as of February 1, 2018 that is not a rural hospital or a low-volume hospital on that date.

(ii) A hospital that is a rural hospital or low-volume hospital with a CCN primary address located in a mandatory MSA that makes an election to participate in the CJR model in accordance with § 510.115.

(iii) A hospital with a CCN primary address located in a voluntary MSA that makes an election to participate in the CJR model in accordance with § 510.115.

* * * * *

Voluntary MSA means an MSA designated by CMS as a voluntary participation MSA in accordance with § 510.105(a).

■ 3. Section 510.105 is amended by revising paragraph (a) to read as follows:

§ 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.

(1) All counties within each of the selected MSAs are selected for inclusion in the CJR model.

(2) Beginning with performance year 3, the selected MSAs are designated as either mandatory participation MSAs or voluntary participation MSAs.

* * * * *

■ 4. Section 510.115 is added to read as follows:

§ 510.115 Voluntary participation election.

(a) *General.* To continue participation in performance year 3 and participate in performance year 4 and performance year 5, the following hospitals must submit a written participation election letter as described in paragraph (c) of this section during the voluntary participation election period specified in paragraph (b) of this section:

(1) Hospitals (other than those excluded under § 510.100(b)) with a CCN primary address in a voluntary MSA.

(2) Low-volume hospitals with a CCN primary address in a mandatory MSA.

(3) Rural hospitals with a CCN primary address in a mandatory MSA.

(b) *Voluntary participation election period.* The voluntary participation election period begins on January 1, 2018 and ends on January 31, 2018.

(c) *Voluntary participation election letter.* The voluntary participation election letter serves as the model participation agreement. CMS accepts the voluntary participation election letter if the letter meets all of the following criteria:

(1) Includes the following:

(i) Hospital name.

(ii) Hospital address.

(iii) Hospital CCN.

(iv) Hospital contact name, telephone number, and email address.

(v) Model name (that is, CJR model).

(2) Includes a certification that the hospital will—

(i) Comply with all applicable requirements of this part and all other laws and regulations applicable to its participation in the CJR model; and

(ii) Submit data or information to CMS that is accurate, complete and truthful, including, but not limited to, the participation election letter and any quality data or other information that CMS uses in its reconciliation processes.

(3) Is signed by the hospital administrator, CFO or CEO.

(4) Is submitted in the form and manner specified by CMS.

■ 5. Section 510.120 is amended by removing paragraph (b)(4), revising paragraph (c), and adding paragraphs (d) and (e) to read as follows:

§ 510.120 CJR participant hospital CEHRT track requirements.

* * * * *

(c) *Clinician engagement list.* Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician engagement list in a form and manner specified by CMS on a no more than quarterly basis. This list must include the following information on individuals for the period of the performance year specified by CMS:

(1) For each physician, nonphysician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS but who does have a contractual relationship with the participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the performance year specified by CMS:

(i) The name, TIN, and NPI of the individual.

(ii) The start date and, if applicable, the end date for the contractual relationship between the individual and participant hospital.

(2) [Reserved]

(d) *Attestation to no individuals.* If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) or paragraph (c) of this section, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report.

(e) *Documentation requirements.* (1) Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use, clinician financial

arrangements lists, and clinician engagement lists.

(2) The participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

■ 6. Section 510.210 is amended by revising paragraph (b) to read as follows:

§ 510.210 Determination of the episode.

* * * * *

(b) *Cancellation of an episode.* The episode is canceled and is not included in the determination of NPRA as specified in § 510.305 if any of the following occur:

(1) The beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in § 510.205.

(ii) Is readmitted to any participant hospital for another anchor hospitalization.

(iii) Initiates an LEJR episode under BPCI.

(iv) Dies.

(2) For performance year 3, the participant hospital did not submit a participation election letter that was accepted by CMS to continue participation in the model.

■ 7. Section 510.300 is amended by revising paragraphs (b)(6) to read as follows:

§ 510.300 Determination of quality-adjusted episode target prices.

* * * * *

(b) * * *

(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, with certain modifications, the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

* * * * *

■ 8. Section 510.305 is amended by revising paragraphs (d)(1) and (e)(1)(i) and adding paragraph (k) to read as follows:

§ 510.305 Determination of the NPRA and reconciliation process.

* * * * *

(d) * * *

(1) Beginning 2 months after the end of each performance year, CMS does all of the following:

(i) Performs a reconciliation calculation to establish an NPRA for each participant hospital.

(ii) For participant hospitals that experience a reorganization event in which one or more hospitals reorganize under the CCN of a participant hospital performs—

(A) Separate reconciliation calculations (during both initial and subsequent reconciliations for a performance year) for each predecessor participant hospital for episodes where anchor hospitalization admission occurred before the effective date of the reorganization event; and

(B) Reconciliation calculations (during both initial and subsequent reconciliations for a performance year) for each new or surviving participant hospital for episodes where the anchor hospitalization admission occurred on or after the effective date of the reorganization event.

* * * * *

(e) * * *

(1) * * *

(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 or the amount determined in paragraph (k) of this section for episodes affected by extreme and uncontrollable circumstances.

* * * * *

(k) *Extreme and uncontrollable circumstances adjustment.* (1) The episode spending adjustments specified in paragraph (k)(2) of this section apply for a participant hospital that has a CCN primary address that meets both of the following:

(i) Is located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135; and

(ii) Is located in a county, parish, or tribal government designated in a major disaster declaration under the Stafford Act.

(2)(i) For a non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300.

(ii) For a fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before or after the date that the emergency period (as defined in section 1135(g) of the Act) begins, actual episode payments are capped at the target price determined for that episode under § 510.300.

■ 9. Section 510.410 is amended by adding paragraph (b)(1)(i)(G) to read as follows:

§ 510.410 Compliance enforcement.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(G) Failing to participate in CJR model-related evaluation activities conducted by CMS or its contractors or both.

* * * * *

■ 10. Section 510.605 is amended by revising paragraph (c)(2) to read as follows:

§ 510.605 Waiver of certain telehealth requirements.

* * * * *

(c) * * *

(2) CMS waives the payment requirements under section 1834(m)(2)(B) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to this model.

* * * * *

PART 512—[Removed and Reserved]

■ 11. Part 512 is removed and reserved.

Dated: November 22, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 28, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–25979 Filed 11–30–17; 8:45 am]

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