

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS-1461-F]

RIN 0938-AS06

Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

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

ACTION: Final rule.

SUMMARY: This final rule addresses changes to the Medicare Shared Savings Program including provisions relating to the payment of Accountable Care Organizations participating in the

Medicare Shared Savings Program. Under the Medicare Shared Savings Program, providers of services and suppliers that participate in an Accountable Care Organizations continue to receive traditional Medicare fee-for-service payments under Parts A and B, but the Accountable Care Organizations may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

DATES: Effective Dates: With the exception of the amendments to §§ 425.312, 425.704, and 425.708, the provisions of this final rule are effective on August 3, 2015. The amendments to § 425.312 and § 425.708 are effective November 1, 2015. The amendments to § 425.704 are effective January 1, 2016.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table

1) that lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

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SUPPLEMENTARY INFORMATION:

Table 1 lists key changes that have an applicability date or effective date other than 60 days after the date of publication of this final rule. By indicating a provision is applicable to a performance year (PY) or agreement period, activities related to implementation of the policy may precede the start of the performance year (in the case of an upcoming year) or agreement period or follow the conclusion of the performance year (in the case of a past year) or the agreement period.

TABLE 1—APPLICABILITY AND EFFECTIVE DATES OF SELECT PROVISIONS OF THE FINAL RULE

Preamble section	Section title/description	Effective date	Applicability date
II.B.1	Agreement Requirements (§ 425.116(a) and (b))		PY 2017 and subsequent performance years.
II.D.2	Provision of Aggregate and Beneficiary Identifiable Data (§ 425.702(c)(1)(ii)).		PY 2016 and subsequent performance years.
II.D.3	Claims Data Sharing (§ 425.704)	1/1/2016	
II.D.3	Beneficiary Opportunity to Decline Claims Data Sharing (§ 425.312 and § 425.708).	11/1/2015	
II.E.3	Definitions of Primary Care Physician and Primary Care Services (§ 425.20).		PY 2016 and subsequent performance years.
II.E.4	Consideration of Physician Specialties and Non-Physician Practitioners in the Assignment Process (§ 425.402(b)).		PY 2016 and subsequent performance years.
II.F.2	Modifications to the Track 2 Financial Model (§ 425.606(b)(1)(ii))		Agreement periods starting on or after January 1, 2016.
II.F.7	Waivers of payment rules or other Medicare requirements (§ 425.612)		PY 2017 and subsequent performance years.

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Regulations Text

Acronyms

- ACO Accountable Care Organization
- CAHs Critical Access Hospitals
- CCM Chronic Care Management
- CEHRT Certified Electronic Health Record Technology
- CG-CAHPS Clinician and Group Consumer Assessment of Health Providers and Systems
- CHIP Children's Health Insurance Program
- CMP Civil Monetary Penalties
- CMS Centers for Medicare & Medicaid Services
- CNM Certified Nurse Midwife
- CMS-HCC CMS Hierarchal Condition Category
- CPT [Physicians] Current Procedural Terminology (CPT codes, descriptions and other data only are copyright 2013 American Medical Association. All rights reserved.)
- CWF Common Working File
- DHHS Department of Health and Human Services
- DOJ Department of Justice
- DSH Disproportionate Share Hospital
- DUA Data Use Agreement
- EHR Electronic Health Record
- ESRD End Stage Renal Disease
- ETA Electing Teaching Amendment
- FFS Fee-for-service
- FQHCs Federally Qualified Health Centers
- FTC Federal Trade Commission
- GPCI Geographic Practice Cost Index
- GPRO Group Practice Reporting Option
- HCC Hierarchal Condition Category
- HCPCS Healthcare Common Procedure Coding System
- HICN Health Insurance Claim Number
- HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)
- HVBP Hospital Value-based Purchasing
- IPA Independent Practice Association
- IPPS Inpatient Prospective Payment System
- IRS Internal Revenue Service
- MA Medicare Advantage
- MedPAC Medicare Payment Advisory Commission
- MLR Minimum Loss Rate
- MSP Medicare Secondary Payer
- MSR Minimum Savings Rate
- MU Meaningful Use
- NCQA National Committee for Quality Assurance

NP Nurse Practitioner
 NPI National Provider Identifier
 NQF National Quality Forum
 OIG Office of Inspector General
 PA Physician Assistant
 PACE Program of All Inclusive Care for the Elderly
 PECOS Provider Enrollment, Chain, and Ownership System
 PFS Physician Fee Schedule
 PGP Physician Group Practice
 PHI Protected Health Information
 PPS Prospective Payment System
 PQRS Physician Quality Reporting System
 PRA Paperwork Reduction Act
 PSA Primary Service Areas
 PY Performance year
 RHCs Rural Health Clinics
 RIA Regulatory Impact Analysis
 SNFs Skilled Nursing Facilities
 SSA Social Security Act
 SSN Social Security Number
 TIN Taxpayer Identification Number
 VM Value Modifier

CPT (Current Procedural Terminology) Copyright Notice

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

Section 1899 of the Social Security Act (the Act) established the Medicare Shared Savings Program (Shared Savings Program), which promotes accountability for a patient population, fosters coordination of items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient health care service delivery. On December 8, 2014, a proposed rule entitled “Medicare Shared Savings Program: Accountable Care Organization” appeared in the **Federal Register** (79 FR 72760) (December 2014 proposed rule). The final rule entitled “Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations,” which appeared in the **Federal Register** on November 2, 2011 (76 FR 67802) (November 2011 final rule) established the original regulations implementing Shared Savings Program. In the December 2014 proposed rule, we proposed to make revisions to some key policies adopted in the November 2011 final rule (76 FR 67802) to incorporate

in our regulations certain guidance that we have issued since the Shared Savings Program was established, and to add new policies to support program compliance and growth.

Our intent in this rulemaking is to make refinements to the Shared Savings Program, to encourage continued and enhanced stakeholder participation, to reduce administrative burden for ACOs while facilitating their efforts to improve care outcomes, and to maintain excellence in program operations while bolstering program integrity.

2. Summary of the Major Provisions

The policies adopted in this final rule codify existing guidance, reduce administrative burden and improve program function and transparency in the following areas: (1) Data-sharing requirements; (2) eligibility and other requirements related to ACO participants and ACO providers/suppliers including clarification of definitions, ACO participant and ACO provider/supplier agreement requirements, identification and reporting of ACO participants and ACO providers/suppliers, including managing changes to the list of ACO participants and ACO providers/suppliers; (3) clarifications and updates to application requirements; (4) eligibility requirements related to the ACO's number of beneficiaries, required processes for coordinating care, the ACO's legal structure and governing body, and its leadership and management structure; (5) the assignment methodology; (6) methodology for determining ACO financial performance; (7) issues related to program integrity and transparency such as public reporting, terminations, and reconsideration review. To achieve these goals, we proposed and are making the following major modifications to our current program rules:

- Clarifying and codifying current guidance related to ACO participant agreements and issues related to the ACO participant and ACO provider/supplier lists. For example, we are finalizing rules for modifying the ACO participant list and requirements related to specific language that must appear in the ACO participant agreements.
- Adding a process for an ACO to renew its 3-year participation agreement for an additional agreement period. Specifically, we articulate rules for renewing the 3 year agreement, including factors that CMS will use to determine whether an ACO may renew its 3-year agreement, such as the ACO's history of compliance with program rules.

- Adding, clarifying, and revising the beneficiary assignment algorithm, including the following:

- ++ Updating the CPT codes that will be considered to be primary care services. Specifically, we are finalizing a policy that includes TCM codes (CPT codes 99495 and 99496) and the CCM code (CPT code 99490) in the definition of primary care services.

- ++ Modifying the treatment of claims submitted by certain physician specialties, NP, PAs, and CNSs in the assignment algorithm. Specifically, we are finalizing a policy that would use primary care services furnished by primary care physicians, NPs, PAs, and CNSs under step 1 of the assignment process, after having identified beneficiaries who received at least one primary care service by a physician in the ACO. Additionally, we are finalizing a policy that would exclude certain services provided by certain physician specialties from step 2 of the assignment process.

- ++ Clarifying how primary care services furnished in federally qualified health centers (FQHCs) and rural health clinics (RHCs) are considered in the assignment process.

- Expanding the kinds of beneficiary-identifiable data that will be made available to ACOs in various reports under the Shared Savings Program as well as simplifying the process for beneficiaries to decline claims data sharing to reduce burden and confusion.

- Adding or changing policies to encourage greater ACO participation in risk-based models by—

- ++ Offering the opportunity for ACOs to continue participating under a one-sided participation agreement after their first 3-year agreement. Specifically, we are finalizing a policy that would permit ACOs to participate in an additional agreement period under one-sided risk with the same sharing rate (50 percent) as was available to them under the first agreement period; and

- ++ Modifying the existing two-sided performance-based risk track (Track 2). Specifically, under Track 2, an ACO will have the choice of several symmetrical MSR/MLR options that will apply for the duration of its 3-year agreement period.

- ++ Offering an alternative performance-based risk model referred to as Track 3. Specifically, we are finalizing the option for ACOs to participate under a two-sided risk model that would incorporate a higher sharing rate (75 percent), prospective assignment of beneficiaries, and the opportunity to apply for a programmatic waiver of the 3-day SNF rule in order to permit payment for otherwise-

covered SNF services when a prospectively assigned beneficiary is admitted to a SNF without a prior 3-day inpatient stay. ACOs in this track will also have the choice of several symmetrical MSR/MLR options that will apply for the duration of their 3-year agreement period.

In addition, in the December 2014 proposed rule we sought comment on a number of options that we had been considering in order to encourage ACOs to take on two-sided performance-based risk under the Shared Savings Program. Based on public comments, we are finalizing the following:

- Resetting the benchmark in a second or subsequent agreement period by integrating previous financial performance and equally weighting benchmarks for subsequent agreement periods; and
- The use of programmatic waiver authority to improve participation in Track 3 by offering regulatory relief from requirements related to the SNF 3-day stay rule.
- We intend to address other modifications to program rules in future rulemaking in the near term to improve ACO willingness to take on performance-based risk including: Modifying the assignment methodology to hold ACOs accountable for beneficiaries that have designated ACO practitioners as being responsible for their care; waiving the geographic requirement for use of telehealth services; and modifying the methodology for resetting benchmarks by incorporating regional trends and costs.

3. Summary of Costs and Benefits

As detailed in Table 10 in section IV. of this final rule, by including the changes detailed in this final rule, the total aggregate median impact would increase to \$780 million in net federal savings for CYs 2016 through 2018. Such median estimated federal savings are \$240 million greater than the \$540 million median net savings estimated at baseline absent the changes adopted in this final rule. A key driver of the anticipated increase in net savings is improved ACO participation levels in a second agreement period. We estimate that at least 90 percent of eligible ACOs will renew their participation in the Shared Savings Program when presented with the new options, primarily under Track 1 and, to a lesser extent, under Track 3. This expansion in the number of ACOs willing to continue their participation in the program is estimated to result in additional improvements in care efficiency of a magnitude significantly greater than the

reduced shared loss receipts estimated at baseline and the added shared savings payments flowing from a higher sharing rate in Track 3 and continued one-sided sharing available in Track 1, with all three tracks operating under generally more favorable rebasing parameters including equal base year weighting and adding a portion of savings from the prior agreement period to the baseline.

In addition, at the anticipated mean participation rate of ACOs in the Shared Savings Program, participating ACOs may experience an estimated aggregate average start-up investment and ongoing operating cost of \$822 million for CYs 2016 through 2018. Lastly, we estimate an aggregate median impact of \$1,130 million in shared savings payments to participating ACOs in the Shared Savings Program for CYs 2016 through 2018. The 10th and 90th percentiles of the estimate distribution, for the same time period, yield shared savings payments to ACOs of \$960 million and \$1,310 million, respectively. Therefore, the total median ACO shared savings payments of \$1,130 million during CYs 2016 through 2018, net of a median \$30 million shared losses, coupled with the aggregate average start-up investment and ongoing operating cost of \$822 million yields a net private benefit of \$278 million.

B. Background

1. General Background

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of Pub. L. 111–148. Collectively known as the Affordable Care Act, these public laws include a number of provisions designed to improve the quality of Medicare services, support innovation and the establishment of new payment models, better align Medicare payments with provider costs, strengthen Medicare program integrity, and put Medicare on a firmer financial footing.

2. Statutory Basis for the Medicare Shared Savings Program

Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding new section 1899 to the Act to establish a Shared Savings Program. This program is a key component of the Medicare delivery system reform initiatives included in the Affordable Care Act and is a new approach to the delivery of health care.

3. Overview of the Medicare Shared Savings Program

The purpose of the Shared Savings Program is to promote accountability for a population of Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and promote higher value care. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare. Under the Shared Savings Program, ACOs share in savings only if they meet both the quality performance standards and generate shareable savings. Consistent with the purpose of the Shared Savings Program, we focused on developing policies aimed at achieving the three-part aim consisting of: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in expenditures.

We viewed the November 2011 final rule as a starting point for the program, and because of the scope and scale of the program and our limited experience with shared savings initiatives under FFS Medicare, we built a great deal of flexibility into the program rules. We anticipated that subsequent rulemaking for the Shared Savings Program would be informed by lessons learned from our experience with the program as well as from testing through the Pioneer ACO Model and other initiatives conducted by the Center for Medicare and Medicaid Innovation (CMS Innovation Center) under section 1115A of the Act.

Over 400 organizations are now participating in the Shared Savings Program. We are gratified by stakeholder interest in this program. As evidenced by the high degree of interest in participation in the Shared Savings Program, we believe that the policies adopted in the November 2011 final rule are generally well-accepted. However, in light of additional experience we have gained during the first few years of the Shared Savings Program, we identified several policy areas for revision in the December 2014 proposed rule (79 FR 72760).

II. Provisions of the Proposed Rule and the Analysis of and Responses to Public Comments

We received a total of 275 timely comments on the December 8, 2014 proposed rule (79 FR 72760). Stakeholders offered comments that addressed both high level issues related to the goals of the Shared Savings Program as well as our specific proposals and request for comment. We

extend our deep appreciation to the public for their interest in the program and the many thoughtful comments that were made to our proposed policies. In some instances, the public comments offered were outside the scope of the proposed rule (for example, suggested revisions to the physician fee schedule or comments regarding the delivery of specific health care services under other Medicare payment systems). These comments will not be addressed in this final rule, but we have shared them with the appropriate subject matter experts in CMS. Summaries of the public comments that are within the scope of this rule and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. In the introduction to section II of this final rule, we address several global comments related to the Shared Savings Program. The remainder of this section of the final rule is organized to give an overview of each issue and the relevant proposals, to summarize and respond to public comments on the proposals, and to describe our final policy decisions based upon our review of the public comments received.

Comment: Several commenters discussed the future of the Shared Savings Program and its sustainability over the long term. Some commenters requested that CMS articulate a clear plan for the future of the program. Others recommended that CMS engage stakeholders in a dialogue on how CMS intends to design a sustainable Accountable Care Organization (ACO) model that would permit continued participation by ACOs. While some commenters were supportive of and looked at the proposed rule as a good beginning in the dialogue on how to improve the sustainability of the program, other commenters suggested that the proposed rule did not go far enough to correct what they described as the program's misguided design elements.

Several commenters offered opinions or suggestions about the interrelationship of the Shared Savings Program and other Medicare programs and models such as Medicare Advantage, the Pioneer ACO Model, the bundled payment model, and others. Some commenters advocated for speedy incorporation of alternative payment models under section 1899(i) of the Act's authority while others suggested that CMS engage in additional discussion with stakeholders and testing before implementing such changes into the Shared Savings Program in order to ensure protection of the Trust Fund and beneficiaries.

Commenters suggested that CMS continue to consider alignment with other Medicare initiatives and payment models, and to coordinate with commercial payers to align requirements for multi-payer ACOs. In particular, some commenters explained the need for CMS to ensure a level playing field and align the requirements that apply to ACOs and Medicare Advantage plans, particularly with respect to the following:

- Availability of programmatic waivers (and more generally regulatory flexibility).
- Benchmarks (particularly benchmarks based on regional costs).
- Risk adjustment.
- Financial reserve requirements
- Quality standards.
- Beneficiary satisfaction.
- Beneficiary choice.

Commenters expressed concern that misalignment between the Shared Savings Program, other Medicare programs, and commercial programs could have unintended effects on healthcare market dynamics and for the care of beneficiaries.

Response: In 2011, Medicare made almost no payments to providers through alternative payment models, but today such payments represent approximately 20 percent of Medicare payments. Earlier this year, the Secretary announced the ambitious goal of tying 30 percent of Medicare FFS payments to quality and value by 2016 and by 2018 making 50 percent of payments through alternative payment models, such as the Shared Savings Program, created by the Affordable Care Act (<http://www.hhs.gov/news/press/2015pres/03/20150325b.html>). With over 400 ACOs serving over 7 million beneficiaries, the Shared Savings Program plays an important role in meeting the Secretary's recently articulated goal.

As stated during the 2011 rulemaking process, we continue to believe that the Shared Savings Program should provide an entry point for all willing organizations who wish to move in a direction of providing value-driven healthcare. We are also interested in encouraging these organizations to progress to greater performance-based risk to drive quality improvement and efficiency in care delivery. For this reason, we established both a shared savings only (one-sided) model and a shared savings/losses (two-sided) model. This structure provides a pathway for organizations to increasingly take on performance-based risk. In this final rule, we build on these principles and are finalizing a set of

policies that we believe aligns with and will advance the Secretary's goals.

Taken together, the comments illuminate overarching issues which require a balance of competing factors and the specific interests of many different stakeholders. We agree with stakeholders that the Shared Savings Program must be structured in a way that that balances various stakeholder interests in a way that both encourages new and continued provider participation in the program and protects beneficiaries with original FFS Medicare and the Medicare Trust Funds. We believe that many design elements discussed in the proposed rule hold promise and deserve continued consideration. We note that many of these suggestions raised by stakeholders are already in the planning stage or being tested in various CMS Innovation Center models, such as the Pioneer Model and the Next Generation ACO Model (announced on March 10, 2015). Testing these designs in various payment models through the CMS Innovation Center is important because it will permit us to make adjustments as needed to ensure that the models work for providers and protect beneficiaries and the Trust Funds. CMS Innovation Center testing will also permit a transparent and fulsome articulation of the design elements in future rulemaking that allows for sufficient public notice and comment prior to broader implementation in the Shared Savings Program. We fully intend to raise many of the design elements suggested by commenters in future rulemaking as the program matures.

We also continue to believe in the importance of maintaining distinctions between the accountable care model in the Shared Savings Program and managed care, such as Medicare Advantage. In the November 2011 final rule (76 FR 67805), we stated that the Shared Savings Program is not a managed care program like the Medicare Advantage program. Medicare FFS beneficiaries retain all rights and benefits under traditional Medicare. Medicare FFS beneficiaries retain the right to see any physician of their choosing, and they do not enroll in the Shared Savings Program. Unlike managed care settings, the assignment of beneficiaries to a Shared Savings Program ACO does not mean that beneficiaries must receive care only from ACO providers/suppliers, nor does it mean that beneficiaries must enroll in the ACO or the Shared Savings Program. The Shared Savings Program is also not a capitated model; providers and suppliers continue to bill and receive FFS payments rather than receiving

lump sum payments based upon the number of assigned beneficiaries. The Shared Savings Program is designed to enhance patient-centered care. For example, it encourages physicians, through the eligibility requirements (for example, the care processes required at § 425.112), to include their patients in decision-making about their health care. While we frequently relied on our experience in other Medicare programs, including Medicare Advantage, to help develop program requirements and design elements for the Shared Savings Program, many Shared Savings Program requirements deviate from those in the other programs precisely because the intent of this program is not to recreate or replace Medicare Advantage.

Finally, we appreciate commenters' concerns that misalignment in incentives across Medicare initiatives has the potential to create unintended consequences for healthcare market dynamics (for example, between Medicare FFS and Medicare Advantage) and for the care of beneficiaries. We believe these concerns underscore the need to take a measured approach to implementing changes into the Shared Savings Program. We also appreciate commenters' enthusiasm for multipayer ACOs, including recommendations for greater alignment between Medicare and private sector initiatives. We are interested in engaging private sector leaders to build on the success of the Shared Savings Program and other alternative payment models to make value-driven care scalable outside of Medicare's purview. To accomplish this, the Secretary recently announced the creation of a Health Care Payment Learning and Action Network. Through the Learning and Action Network, HHS will work with private payers, employers, consumers, providers, states and state Medicaid programs, and other partners to expand alternative payment models through their own aligned work. As articulated by the Secretary, the public and private sectors have a common interest in building a health care system that delivers better care, spends health care dollars more wisely, and results in healthier people.¹ Beginning with the November 2011 final rule, we have sought to align with other CMS and private sector initiatives, beginning with our selection of quality measures. As the program evolves, we look forward to learning from the Learning and Action Network as well as various CMS Innovation Center initiatives that are planning or already

testing multipayer concepts and we intend to revisit this issue in future rulemaking.

Comment: Many commenters were supportive of both the Shared Savings Program and our proposals in the December 2014 proposed rule. However, many commenters expressed general concerns related to the financial model as currently designed, stating that the Shared Savings Program places too much risk and burden on providers with too little opportunity for reward in the form of shared savings. Commenters encouraged CMS to modify the Shared Savings Program rules, particularly in a manner that would increase the financial opportunities for ACOs and attract more participants, which would sustain and improve long term participation. A few commenters suggested that CMS act quickly in improving the program's financial models, absent which existing ACOs may decide that the financial risks outweigh the benefits and choose to withdraw from the program.

Commenters offered a variety of specific suggestions for improving the financial sustainability of the program, many of which are related to our proposals and request for comment and are addressed in section II.F. of this final rule. Some commenters recommended that CMS combine various design elements, stating that such changes would be key to encouraging ongoing participation in the program and driving meaningful change by ACOs. Some commenters offered specific suggestions for improving provider or ACO participation. For example, some commenters recommended that CMS provide up-front funding, consider the effect of seasonal commuter beneficiaries ("snowbirds") on an ACO's performance cost calculations, permit providers to participate in more than one Medicare initiative involving shared savings, or permit certain groups (such as rural ACOs) to participate in Track 1 indefinitely or create a special rural-only track.

Several commenters suggested that the program incorporate more explicit financial incentives for higher quality performance (for example, modifying the ACO's Minimum Savings Rate (MSR), while others requested retention of the current approach but suggested that CMS offer an even higher sharing rate to ACOs demonstrating high quality. Others recommended rewarding high quality organizations regardless of their financial performance.

Response: We believe the changes to the Shared Savings Program tracks and other design elements that recognize an

ACO's efforts finalized in section II.F. of this final rule address commenters' requests for improvements to the program's tracks and program sustainability overall. As explained in detail in section II.F., this final rule creates additional opportunities for ACOs to be financially rewarded for their achievement of the three-part aim, including the following:

- A second agreement period under the one-sided model for eligible Track 1 ACOs, with the opportunity to achieve a maximum sharing rate of 50 percent.
- Greater flexibility in choice of MSR/ Minimum Loss Rate (MLR) under a two-sided model; and the chance for greater reward (in relation to greater risk) under the newly established Track 3.

Additionally, we are finalizing policies related to resetting ACO benchmarks, including equal weighting the benchmark years, and accounting for shared savings generated under the prior agreement period. The revisions to the methodology for resetting the benchmark are expected to slow the rate at which the benchmark decreases in comparison to rebasing under the program's current methodology. Finally, we note that many ACOs that are currently participating in the program have had access to up-front funding through the CMS Innovation Center Advance Payment Model. The CMS Innovation Center is currently offering additional qualified ACOs the opportunity to apply for up-front funding through the ACO Investment Model. We believe these changes, taken together, will improve the opportunity for ACOs to realize rewards under the program.

We intend to continue to update and revise the Shared Savings Program over time as we gain experience and gain insights from testing that is ongoing in the CMS Innovation Center. In particular, as discussed in more detail in section II.F. of this final rule, based on the comments we received in the proposed rule and our own continued analysis, we believe that in order to encourage ACOs to achieve and maintain savings, it is important to move quickly to a benchmarking methodology that sets and updates ACO benchmarks largely on the basis of trends in regional FFS costs, rather than ACO's historical costs. For this reason we intend to propose and seek comment on a new benchmarking methodology later this summer. We anticipate that the revised benchmark rebasing methodology incorporating the ACO's historical costs and regional FFS costs and trends would apply to ACOs beginning new agreement periods in 2017 or later. ACOs beginning a new

¹ March 25, 2015 HHS press release. <http://www.hhs.gov/news/press/2015pres/03/20150325b.html>.

agreement period in 2016 would convert to the revised methodology at the start of their third agreement period in 2019.

Comment: Several commenters expressed concern regarding the timing of the finalization of program rules in relation to the ability of an ACO or applicant to adjust to them, or the impact that may have on the willingness of organizations to take on greater performance-based risk. Commenters were particularly concerned that ACOs with agreement periods ending in 2015 would not have an adequate amount of time to understand the implications of the final regulations (particularly if moving to two-sided risk) before having to seek renewal of their agreements during the summer of 2015.

Response: We are aware of the timing concerns expressed by stakeholders and strive to give ACOs ample time to make decisions that are in the best interest of their patients, providers and organization. Therefore, we intend to implement final policies with these timing considerations in mind. Most of the policies will take effect for the 2016 performance year; for example, our assignment methodology changes. However, we will defer implementation of some policies, recognizing that ACOs may need more time to come into compliance with the requirements. For example, we believe that modifying agreements with ACO participants and ACO providers/suppliers to comply with the requirements of new § 425.116 may take time. Accordingly, we will not require ACOs to comply with § 425.116(a) and (b) until the 2017 performance year in the case of ACO participants and ACO providers/suppliers that have already agreed to participate in the Shared Savings Program. Similarly, we will not require organizations that are applying or renewing for a January 1, 2016 start date to submit agreements with the updated language as part of the 2016 application and renewal process which occurs the summer and fall of 2015. However, we will expect and require that ACO participant agreements submitted for our review for purposes of adding new ACO participants to the ACO's list of ACO participants for performance years 2017 and subsequent years will comply with the new rules. For example, if an ACO submits a request to add an ACO participant to its ACO participant List for the 2017 performance year during 2016, the ACO participant agreement must meet the requirements established in this final rule. Similarly, because of the operational complexity of the SNF 3-day rule waiver, we will defer implementation of that policy to no earlier than the 2017 performance year.

We intend to develop and update guidance and operational documents as the new policies become effective.

Comment: Several commenters suggested ways for the Shared Savings Program to increase or ensure beneficiary engagement. For example, commenters suggested permitting ACOs to financially reward beneficiaries for choosing low cost options or healthy behaviors, allowing ACOs to remove non-engaged beneficiaries by permitting the ACO to dismiss "non-compliant" beneficiaries, allowing ACOs more flexibility to interact with their beneficiary population to generate a more patient-centric program, and excluding certain vulnerable patient populations from ACO costs until ACOs develop a better track record of treating these patients.

Several commenters made comments related to Medicare beneficiaries and their interaction with the ACO. A commenter stated that one of the major challenges for ACOs is "getting beneficiaries to understand that they are a part of an ACO" and that they are encouraged to receive all of their health care from ACO participating professionals and suppliers. The commenter suggested that CMS develop educational documents/resources for assigned beneficiaries that clearly outline the advantages and benefits of obtaining health care from their assigned ACO. On the other hand, a few other commenters expressed concerns that the Shared Savings Program regulations do not reinforce the concept that beneficiaries can get care outside the ACO. A few commenters requested that CMS perform various forms of monitoring activities to ensure that ACOs are providing open access to all beneficiaries. Commenters requested that we strictly monitor both referral patterns and any avoidance activities in order that all beneficiaries have access to quality care.

Response: We recognize that beneficiary engagement is an important element in the ACO's ability to meet its goal of improving quality and reducing costs. For this reason, the statute and our program rules require ACOs to develop a process to promote patient engagement. We believe patient engagement works best at the point of care and the development of the patient-doctor relationship. Several ACOs that achieved first year success in the program have observed that patient engagement improves when engaged providers improve patient care. However, we will continue to consider how CMS can best support ACO efforts while ensuring beneficiary and Trust Funds protections.

Additionally, as noted in this section and by some commenters, the Shared Savings Program is not a managed care program. Medicare FFS beneficiaries in the Shared Savings Program retain all rights and benefits under traditional Medicare. Medicare FFS beneficiaries retain the right to see any physician of their choosing, and they do not enroll in the Shared Savings Program. Unlike a managed care program, the assignment of beneficiaries to a Shared Savings Program ACO does not mean that beneficiaries must receive care only from ACO providers/suppliers, nor does it mean that beneficiaries must enroll in the ACO or the Shared Savings Program. Therefore, we develop patient materials with the assistance of the ombudsman's office (for example, the Medicare and You Handbook, required ACO notifications, fact sheets) that state the rights and freedoms of beneficiaries under traditional FFS Medicare. We do not agree that it is appropriate for ACOs or CMS to require beneficiaries to receive all of their care from ACO participating professionals and suppliers. Rather, it is a program requirement that the ACO develop a process to promote care coordination across and among providers and suppliers both inside and outside the ACO.

Finally, although beneficiaries that receive services from ACO professionals continue to retain the freedom to choose their providers, CMS monitors ACOs for prohibited behaviors such as avoidance of at-risk beneficiaries. Several other protections are in place, including a prohibition on beneficiary inducements and on certain required referrals and cost shifting § 425.304. Moreover, providers and suppliers that seek to participate in an ACO undergo screening for program integrity history and may be denied participation in the Shared Savings Program based on the results.

Comment: Many commenters were concerned with what they identified as either a lack of communication from CMS on specific questions or an overall lack of information about the program. Comments requested that CMS provide both general and detailed programmatic information. Others commenters recommended that the best practices that have resulted in shared savings be shared with ACOs and that CMS provide a detailed account of best practices that have been observed by ACOs that generated savings.

Response: We believe that program transparency is important. For this reason, many of the current and newly finalized policies in this rule are designed to promote transparency for

beneficiaries and providers. For example, we have updated our public reporting requirements, codified and updated our requirements for ACO participant agreements, clarified numerous policies, and posted quality and financial information about ACOs on our Web site and Physician Compare (<http://www.medicare.gov/physiciancompare/aco/search.html>). There are many other methods we use to answer questions and assist ACOs participating in the program, including the following:

- Each ACO has a designated CMS Coordinator that develops an ongoing relationship with the ACO and is a direct resource to help ACOs navigate program requirements and deadlines.
- Operational guidance documents and FAQs that are available to ACOs on the ACO portal.
- Weekly newsletters with important information including deadline reminders.
- A dedicated CMS Web page (<https://www.cms.gov/sharesavingsprogram/>) with program information, timelines, FAQs.
- A dedicated email box for ACOs to submit questions for subject matter experts to address.
- Frequent webinars that provide detailed information on program operations and methodologies, the opportunity to speak with CMS staff, and peer-to-peer learning sessions. We recognize that in spite of these efforts, there may be additional opportunities to improve program transparency. Therefore, we thank the commenters for their suggestions and will continue to look for ways we can engage with ACOs.

We also note that we invite all ACOs to participate in learning best practices through ACO Learning System activities. The ACO Learning System was developed to provide ACOs with peer-to-peer learning opportunities that are in the form of in-person learning sessions and regularly scheduled webinars. This forum provides a unique mechanism for ACOs to share their challenges and successes with other ACOs. Summaries and slides from past sessions are available to participating ACOs through the ACO portal.

A. Definitions

In the November 2011 final rule (76 FR 67802), we adopted definitions of key terms for purposes of the Shared Savings Program at § 425.20. These terms are used throughout this final rule. We encourage readers to review these definitions. Based on our experiences thus far with the Shared Savings Program and inquiries we received regarding the defined terms,

we proposed some additions to the definitions and a few revisions to the existing definitions.

1. Proposed Definitions

We proposed to add several new terms to the definitions in § 425.20. First, we proposed to add a definition of “participation agreement.” Specifically, we proposed to define the term to mean the written agreement required under § 425.208(a) between the ACO and CMS that, along with the regulations at part 425, governs the ACO’s participation in the Shared Savings Program. We further proposed to make conforming changes throughout part 425, replacing references to an ACO’s agreement with CMS with the defined term “participation agreement.” In addition, we proposed to make a conforming change in § 425.204(c)(1)(i) to remove the incorrect reference to “participation agreements” and replace it with “ACO participant agreements.”

We proposed to add the related definition of “ACO participant agreement.” Specifically, we proposed to define “ACO participant agreement” to mean the written agreement between an ACO and an ACO participant required at § 425.116 in which the ACO participant agrees to participate in, and comply with, the requirements of the Shared Savings Program.

As discussed in section II.F. of the proposed rule, we proposed to add a definition for “assignment window,” to mean the 12-month period used to assign beneficiaries to an ACO. This definition was added to accommodate the 12 month period used to assign beneficiaries to Track 1 and 2 ACOs based on a calendar year as well as the off-set 12 month period used to assign beneficiaries prospectively to an ACO in Track 3.

Comment: Many commenters were supportive of the addition of definitions for “participation agreement” and “ACO participant agreement.” Several commenters explicitly stated support for the proposal to define an “assignment window”.

Response: We appreciate stakeholder support for incorporating new definitions in to the Shared Savings Program.

FINAL ACTION: We are finalizing the new definitions of “participation agreement”, “ACO participant agreement”, and “assignment window” as proposed in § 425.20. We believe these definitions will facilitate transparency and a better understanding of the program rules.

2. Proposed Revisions to Existing Definitions

We proposed several revisions to existing definitions. First, we proposed to revise the definition of “ACO participant” to clarify that an ACO participant is an “entity” identified by a Medicare-enrolled TIN. Additionally, we proposed to correct a grammatical error by revising the definition to indicate that one or more ACO participants “compose,” rather than “comprise” an ACO. We noted that a related grammatical error would be corrected at § 425.204(c)(1)(iv). These proposed changes to the definition of “ACO participant” were not intended to alter the way the Shared Savings Program currently operates.

We proposed to revise the definition of “ACO professional” to remove the requirement that an ACO professional be an ACO provider/supplier. We also proposed to revise the definition of “ACO professional” to indicate that an ACO professional is an individual who bills for items or services he or she furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with Medicare regulations. We proposed these modifications because there may be ACO professionals who furnished services billed through an ACO participant’s TIN in the benchmarking years but are no longer affiliated with the ACO participant and therefore are not furnishing services billed through the TIN of the ACO participant during the performance years. These proposed changes to the definition of “ACO professional” are not intended to alter the way the Shared Savings Program currently operates.

We proposed to modify the definition of “ACO provider/supplier” to clarify that an individual or entity is an ACO provider/supplier only when it is enrolled in the Medicare program, bills for items and services furnished to Medicare FFS beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant, and is included on the list of ACO providers/suppliers that is required under the proposed regulation at § 425.118. We stated our belief that an individual or entity should be considered an ACO provider/supplier if he or she previously (for example, during the benchmarking years) reassigned the right to receive Medicare payment to a prospective ACO participant, but is not participating in the activities of the ACO during the ACO’s agreement period by furnishing care to Medicare FFS beneficiaries that

is billed through the TIN of an ACO participant. The proposed modification was intended to clarify that a provider or supplier must bill for items or services furnished to Medicare FFS beneficiaries through the TIN of an ACO participant during the ACO's agreement period in order to be an ACO provider/supplier.

We proposed to modify the definition of "assignment" to mean the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from "ACO professionals." In the proposed rule, we explained that that for purposes of defining assignment, we stated our belief that it is more appropriate to use the term "ACO professional," rather than the term "ACO provider/supplier," because a physician or other practitioner can only be an ACO provider/supplier if he or she bills for items and services through the TIN of an ACO participant during the ACO's agreement period and is included on the list of ACO providers/suppliers required under our regulations. However, there may be an ACO professional who furnishes services billed through an ACO participant's TIN in the performance or benchmarking years but is either not listed on the ACO providers/suppliers list or is no longer billing through the ACO participant's TIN during the performance years and therefore cannot be considered an ACO provider/supplier.

In the interests of clarity, we therefore proposed to modify the definition of assignment to reflect that our assignment methodology takes into account claims for primary care services furnished by ACO professionals, not solely claims for primary care services furnished by physicians in the ACO. This revision would ensure consistency with program operations and alignment with the definition of "ACO professional" since it is the aggregation of the ACO professionals' claims that impacts assignment. We stated that the proposed modification to the definition of "assignment" would more accurately reflect the use of claims for primary care services furnished by ACO professionals that are submitted through an ACO participant's TIN in determining beneficiary assignment in the ACO's benchmark and performance years. Additionally, we proposed to make conforming changes as necessary to the regulations governing the assignment methodology in part 425 subpart E, to revise the references to "ACO provider/supplier" to read "ACO professional."

We proposed a technical revision to the definition of "hospital" for purposes

of the Shared Savings Program. Section 1899(h)(2) of the Act provides that, for purposes of the Shared Savings Program, the term "hospital" means a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act. In the November 2011 final rule (76 FR 67812), we finalized a definition of "hospital" that included only acute care hospitals paid under the hospital inpatient prospective payment system (IPPS). Under this definition, Maryland acute care hospitals would not be considered to be "hospitals" for purposes of the Shared Savings Program because they are subject to a waiver from the Medicare payment methodologies under which they would otherwise be paid. We proposed to clarify that a Maryland acute care hospital is a "hospital" for purposes of the Shared Savings Program. Specifically, we proposed to revise the definition of "hospital" for purposes of the Shared Savings Program to mean a hospital as defined in section 1886(d)(1)(B) of the Act. The proposed regulation is consistent with both the statutory definition of "hospital" for purposes of the Shared Savings Program in section 1899(h)(2) of the Act and the position we have taken in other contexts in referring to subsection (d) hospitals.

We proposed to modify the definition of "primary care services." We refer the reader to section I.E.3. of this final rule for a more detailed discussion of the proposed revision to this definition, which is relevant to the assignment of a Medicare beneficiary to an ACO, as well as responses to comments received on this proposal.

As discussed in greater detail in section I.F. of the proposed rule, we proposed revisions to the definitions of "continuously assigned beneficiary" and "newly assigned beneficiary." These definitions relate to risk adjustment for the assigned population and required minor modification to accommodate the newly proposed Track 3. Specifically, we proposed to replace the reference in these definitions to "most recent prior calendar year" with a reference to "the assignment window for the most recent prior benchmark or performance year." Thus, for Track 3 the reference period for determining whether a beneficiary is newly or continuously assigned would be the most recent prior prospective assignment window (the off-set 12 months) before the assignment window for the current performance year and the reference period for determining whether a Track 1 or 2 beneficiary is newly or continuously assigned would continue to be the most recent prior assignment window (the most recent calendar year).

Finally, in connection with our discussion of the applicability of certain changes that are made to program requirements during the agreement period, we proposed revisions to the definition of "agreement period." Readers should refer to section II.C.4. of this final rule for a discussion of the proposed changes to the definition as well as the responses to comments received on the proposal.

Comment: Many commenters expressed general support for modifications to the definitions. Several commenters expressed support for our proposed revision to the definition of "ACO participant" but suggested that CMS clarify that some ACO participants could be individual providers billing under his or her own Social Security Number, rather than the TIN of an ACO participant. A few commenters expressed support for our proposal to modify the definition of "hospital," stating that this modification will result in clarity for Maryland acute care facility participation in the Shared Savings Program and provide an equal opportunity for all hospitals to form ACOs. A commenter expressed concern that the definitions of "ACO professional, ACO participant and ACO provider/supplier" would "restructure the intended roles of providers within ACOs" and encouraged CMS to develop definitions that would be inclusive rather than exclusive to "protect the inclusive intent of the legislation which recognizes NPs as ACO professionals."

Response: We appreciate the comments we received in favor of our proposals to modify certain definitions. We believe these modifications will improve program transparency and understanding of program rules and respond to stakeholder inquiries. We believe the definitions support and lend transparency to the program rules, are consistent with statutory language, and inclusive of Medicare enrolled providers and suppliers that furnish services to Medicare FFS beneficiaries. We are unclear what the commenter is referring to regarding the "inclusive intent" of the statute and believe we have developed definitions that are consistent with the statutory language. Our definition of an ACO participant includes Medicare enrolled billing TINs through which one or more ACO providers/suppliers bill Medicare. As such, ACOs may include the TIN of solo practitioners on its list of ACO participants because Social Security Numbers (SSNs) and Employer Identification Numbers (EINs) are types of Taxpayer Identification Numbers. Furthermore, we agree with commenters that aligning the program definition of

hospital with the statutory definition will permit Maryland hospitals to form an ACO under our program rules, although we note that current program rules permit such hospitals to be an ACO participant along with other ACO participants that have joined to form an ACO.

FINAL ACTION: We are finalizing the proposed modifications to the definitions of ACO participant, ACO professional, ACO provider/supplier, assignment, hospital, and newly assigned beneficiary and continuously assigned beneficiary, along with necessary conforming changes. We refer the reader to sections II.C. and II.E. of this final rule for a review of comments, responses, and final actions regarding the definitions of “agreement period” and “primary care services.”

B. ACO Eligibility Requirements

1. Agreement Requirements

a. Overview

Section 1899(b)(2)(B) of the Act requires participating ACOs to “enter into an agreement with the Secretary to participate in the program for not less than a 3-year period.” If the ACO is approved for participation in the Shared Savings Program, an executive who has the ability to legally bind the ACO must sign and submit a participation agreement to CMS (§ 425.208(a)(1)). Under the participation agreement with CMS, the ACO agrees to comply with the regulations governing the Shared Savings Program (§ 425.208(a)(2)). In addition, the ACO must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO’s activities agree to comply with the Shared Savings Program regulations and all other applicable laws and regulations (§ 425.208(b) and § 425.210(b)) and to commit to the participation agreement (§ 425.306(a)). The ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance (§ 425.210(a)). As part of its application, we currently require each ACO to submit a sample of the agreement it executes with each of its ACO participants (the “ACO participant agreement”). Also, as part of its application and when requesting the addition of new ACO participants, we require an ACO to submit evidence that it has a signed written agreement with each of its ACO participants. (See guidance on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/>

[sharedsavingsprogram/Downloads/Memo_Additional_Guidance_on_ACO_Participants.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Memo_Additional_Guidance_on_ACO_Participants.pdf)). An ACO’s application to participate in the Shared Savings Program and any subsequent request to add new ACO participants will not be approved if the ACO does not have an agreement in place with each of its ACO participants in which each ACO participant agrees to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program.

In our review of applications to participate in the Shared Savings Program, we received many ACO participant agreements that were not properly executed, were not between the correct parties, lacked the required provisions, contained incorrect information, or failed to comply with § 425.304(c) relating to the prohibition on certain required referrals and cost shifting. When we identified such agreements, ACOs experienced processing delays, and in some cases, we were unable to approve the ACO applicant and its ACO participant or both to participate in the Shared Savings Program. Consequently, we issued guidance for ACO applicants in which we stated the required elements for ACO participant agreements and strongly recommended that ACOs employ good contracting practices to ensure that each of their ACO participant agreements met our requirements (see <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Tips-ACO-Developing-Participant-Agreements.pdf>).

The ACO participant agreements are necessary for purposes of program transparency and to ensure an ACO’s compliance with program requirements. Moreover, many important program operations (including calculation of shared savings, assignment of beneficiaries, and financial benchmarking) use claims and other information that are submitted to CMS by the ACO participant. Our guidance clarifies that ACO participant agreements and any agreements with ACO providers/suppliers must contain the following:

- An explicit requirement that the ACO participant or the ACO provider/supplier will comply with the requirements and conditions of the Shared Savings Program (part 425), including, but not limited to, those specified in the participation agreement with CMS.
- A description of the ACO participants’ and ACO providers’/suppliers’ rights and obligations in and representation by the ACO.

- A description of how the opportunity to get shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to follow the quality assurance and improvement program and evidence-based clinical guidelines.

- Remedial measures that will apply to ACO participants and ACO providers/suppliers who do not comply with the requirements of their agreements with the ACO.

Our guidance also requires that the ACO participant agreements be made directly between the ACO and the ACO participant. We believe it is important that the parties entering into the agreement have a direct legal relationship to ensure that the requirements of the agreement are fully and directly enforceable by the ACO, including the ability of the ACO to terminate an agreement with an ACO participant that is not complying with the requirements of the Shared Savings Program. Therefore, we believe a direct contractual relationship is important. Additionally, a direct contractual relationship ensures that the ACO participant may, if necessary, terminate the agreement with the ACO according to the terms of the agreement without interrupting other contracts or agreements with third parties. Therefore, the ACO and the ACO participant must be the only parties to an ACO participant agreement; the agreements may not include a third party to the agreement. For example, the agreement may not be between the ACO and another entity, such as an independent practice association (IPA) or management company that in turn has an agreement with one or more ACO participants. Similarly, ACOs should not use existing contracts between ACOs and ACO participants that include third parties.

We recognize that contractual agreements do exist between entities (for example, contracts that permit organizations like IPAs to negotiate contracts with health care payers on behalf of individual practitioners). However, because it is important to ensure that there is a direct contractual relationship between the ACO and the ACO participant evidenced by a written agreement, and because ACO participants continue to bill and receive payments as usual under the Medicare FFS rules (that is, there is no negotiation for payment under the program) we believe that typical IPA contracts are inappropriate and unnecessary for purposes of participation in the Shared Savings Program. An ACO and ACO participant may use a contract unrelated to the Shared Savings Program as an

ACO participant agreement only when it is between the two parties and is amended to satisfy the requirements for ACO participant agreements under the Shared Savings Program.

It is the ACO's responsibility to make sure that each ACO participant agreement identifies the parties entering into the agreement using their correct legal names, specifies the term of the agreement, and is signed by both parties to the agreement. We validate the legal names of the parties based on information the ACO submitted in its application and the legal name of the entity associated with the ACO participant's TIN in the Provider Enrollment Chain & Ownership System (PECOS). We reject an ACO participant agreement if the party names do not match our records. It may be necessary for the ACO to execute a new or amended ACO participant agreement.

Although the ACO participant must ensure that each of its ACO providers/suppliers (as identified by a National Provider Identifier (NPI)) has agreed to participate in the ACO and will comply with program rules, the ACO has the ultimate responsibility for ensuring that all the ACO providers/suppliers that bill through the TIN of the ACO participant have also agreed to participate in the Shared Savings Program and comply with our program regulations. The ACO may ensure this by directly contracting with each ACO provider/supplier (NPI) or by contractually requiring the ACO participant to ensure that all ACO providers/suppliers that bill through its TIN have agreed to participate in, and comply with the requirements of, the Shared Savings Program. If the ACO chooses to contract directly with the ACO providers/suppliers, the agreements must meet the same requirements as the agreements with ACO participants. We emphasize that even if an ACO chooses to contract directly with the ACO providers/suppliers (NPIs), it must still have the required ACO participant agreement. In other words, the ACO must be able to produce valid written agreements for each ACO participant and each ACO provider/supplier. Furthermore, since we use TINs (and not merely some of the NPIs that make up the entity identified by a TIN) as the basis for identifying ACO participants, and we use all claims submitted under an ACO participant's TIN for financial calculations and beneficiary assignment, an ACO may not include an entity as an ACO participant unless all Medicare enrolled providers and suppliers billing under that entity's TIN have agreed to participate in the ACO as ACO providers/suppliers.

We proposed to codify much of our guidance regarding the content of the ACO participant and ACO provider/supplier agreements.

b. Proposed Revisions

First, we proposed to add new § 425.116 to set forth the requirements for agreements between an ACO and an ACO participant or ACO provider/supplier. We stated our belief that the new provision would promote a better general understanding of the Shared Savings Program and transparency for ACO participants and ACO providers/suppliers. It was our intent to provide requirements that would facilitate and enhance the relationships between ACOs and ACO participants, and reduce uncertainties and misunderstandings leading to rejection of ACO participant agreements during application review. Specifically, we proposed to require that ACO participant agreements satisfy the following criteria:

- The ACO and the ACO participant are the only parties to the agreement.
- The agreement must be signed on behalf of the ACO and the ACO participant by individuals who are authorized to bind the ACO and the ACO participant, respectively.
- The agreement must expressly require the ACO participant to agree, and to ensure that each ACO provider/supplier billing through the TIN of the ACO participant agrees, to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).
- The agreement must set forth the ACO participant's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in Subpart F, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO participant and its ACO providers/suppliers to participate in other Medicare demonstration projects or programs that involve shared savings.
- The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.
- The agreement must require the ACO participant to update enrollment information with its Medicare Administrative Contractor using the PECOS, including the addition and

deletion of ACO professionals billing through the TIN of the ACO participant, on a timely basis in accordance with Medicare program requirements. The agreement must also require ACO participants to notify the ACO within 30 days after any addition or deletion of an ACO provider/supplier.

- The agreement must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of shared savings payments (that is, the ability of the ACO participant or ACO provider/supplier to receive a distribution of the ACO's shared savings) and termination of the ACO participant agreement, to address non-compliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS.

- The term of the agreement must be for at least 1 performance year and must articulate potential consequences for early termination from the ACO.

- The agreement must require completion of a close-out process upon the termination or expiration of the ACO's participation agreement that requires the ACO participant to furnish data necessary to complete the annual assessment of the ACO's quality of care and addresses other relevant matters.

Although we proposed that the term of an ACO participant agreement be for at least 1 performance year, we stated that we did not intend to prohibit early termination of the agreement. We recognized that there may be legitimate reasons to terminate an ACO participant agreement. However, because care coordination and quality improvement requires commitment from ACO participants, we stated our belief that a minimum requirement of 1 year would improve the likelihood of success in the Shared Savings Program. We also stated that we were considering whether and how ACO participant agreements should encourage participation to continue for subsequent performance years. We sought comment on this issue.

In the case of an ACO that chooses to contract directly with its ACO providers/suppliers, we proposed virtually identical requirements for its agreements with ACO providers/suppliers. We noted that, unlike agreements between the ACO and an ACO participant, agreements with ACO providers/suppliers would not be required to be for a term of at least 1 year, because we did not want to impede individual practitioners from activities such as retirement, reassignment of billing rights, or

changing employers. In the case of ACO providers/suppliers that do not contract directly with the ACO, we considered requiring each ACO to ensure that its ACO participants contract with or otherwise arrange for the services of its ACO providers/suppliers on the same or similar terms as those required for contracts made directly between the ACO and ACO providers/suppliers.

In addition, we proposed to add at § 425.204(c)(6) a requirement that, as part of the application process and upon request thereafter, the ACO must submit documents demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. In the case of ACO participants, we proposed that the evidence to be submitted must, consistent with our past guidance, include sample form agreements together with the first and last (signature) page of each form agreement that has been fully executed by the parties to the agreement. However, we proposed to reserve the right to request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. In addition, we proposed at § 425.116(c) that executed ACO participant agreements would also be submitted when an ACO seeks approval to add new ACO participants. The agreements would be submitted in the same form and manner as set forth in § 425.204(c)(6). Finally, although we would not routinely request an ACO to submit copies of executed agreements the ACO or ACO participants have with the ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities as part of the ACO's application or continued participation in each performance year, we proposed to reserve our right to request this information during the application or renewal process and at any other time for audit or monitoring purposes in accordance with § 425.314 and § 425.316.

We stated our belief that the proposed requirements regarding agreements between ACOs and ACO participants, together with our earlier guidance regarding good contracting practices, would enhance transparency between the ACO, ACO participants, and ACO professionals, reduce turnover among ACO participants, prevent misunderstandings related to participation in the Shared Savings Program, and assist prospective ACOs in submitting complete applications and

requests for adding ACO participants. We stated our belief that codifying these requirements would assist the ACO, ACO participants, and ACO providers/suppliers in better understanding the program and their rights and responsibilities while participating in the program. We solicited comment on the proposed requirements and on whether we should consider additional elements to include in the agreements the ACO has with its ACO participants and ACO providers/suppliers.

Comment: Most commenters agreed with the CMS proposed criteria for ACO participant agreements stating that it is important for each ACO participant to understand its obligations and rights. Additionally, commenters stated that it is "crucial" for all practitioners participating in the ACO to agree to both program participation and compliance with all relevant laws and regulations, and that transparency in the opportunity to receive shared savings is essential for expectations. Some commenters agreed with our proposal for ACO participant agreements to require that ACO participants update enrollment information with their Medicare Administrative Contractor using PECOS within 30 days of any addition/deletion of an ACO provider/supplier. However, several commenters expressed concerns with the general requirement discussed later in this section that ACOs be held responsible for ensuring that ACO participants and ACO providers/suppliers appropriately update PECOS.

Response: We appreciate the general support for our proposals related to ACO participant agreements. We agree with commenters that transparency between ACOs and ACO participants is important. We agree with commenters that it is important for all practitioners participating in the ACO to explicitly agree to both participation and compliance with all relevant laws and regulations. We believe it is important for ACOs to encourage and enforce compliance with all Medicare laws and regulations, including the requirement that Medicare enrolled entities keep Medicare enrollment records updated. Since Medicare already requires enrollment information to be updated within 30 days of a change, we do not believe the 30 day requirement for Medicare enrolled entities to alert PECOS of any additions/deletions is overly burdensome. Moreover, including this requirement in the ACO participant agreement will assist the ACO in reinforcing this requirement as a condition of participation in the ACO and enable the ACO to comply with program rules.

Comment: A commenter stated CMS to include a requirement for ACO participant agreements to specify that a portion of shared savings be shared with ACO providers/suppliers, especially specialists.

Response: We believe maintaining transparency regarding the opportunity to receive shared savings is essential in order to set appropriate expectations for all parties. For this reason, we strongly urge ACOs to be transparent in the agreements that are developed for ACO participants, for example, by clearly articulating expectations for how shared savings will be distributed to ACO participants and ACO providers/suppliers. However, we do not require ACOs to distribute shared savings in a particular manner. We believe it is important to permit ACOs the flexibility to use and distribute shared savings, as long as the methodology complies with applicable law. As explained in the November 2011 final rule, we do not believe we have the legal authority to dictate how shared savings are distributed; however, we believe it is consistent with the purpose and intent of the statute to require the ACO to indicate how it plans to use potential shared savings to meet the goals of the program. We encourage ACOs to be transparent about this plan in its agreements with ACO participants.

Comment: A commenter stated that forcing an entity to remain in an ACO for the duration of the performance year would compromise the goals of the ACO and contribute to administrative burden. Another commenter suggested that CMS finalize an additional requirement for ACO participants to notify the ACO if they wish to terminate prior to the CMS deadlines for subsequent year changes.

Response: We believe it is important for each ACO participant to understand its obligations and rights in detail. We also note that program rules currently require each ACO participant to commit to the 3-year participation agreement that the ACO makes with CMS (§ 425.306(a)). As we stated in the proposed rule, because care coordination and quality improvement requires commitment from ACO participants, we believe that a minimum 1-year term requirement would improve the likelihood of success of the ACO and its ACO participants. For these reasons, we believe it is important to require ACO participant agreements to include the requirement that the agreement must be for at least 1 performance year and address potential consequences for early termination. Rather than compromising the goals of the ACO, we believe this enhances the ACO's ability to achieve its goals. We

may consider in future rulemaking the suggestion to require ACO participants and ACO providers/suppliers to provide some prior notice of termination to the ACO. However, even in the absence of such a requirement, we believe that ACOs will, as a matter of prudent business contracting, incorporate a requirement that ACO participants and ACO providers/suppliers must provide some prior notice of termination to the ACO.

Comment: A commenter requested that CMS more thoroughly consider the required close-out procedures so ACOs could incorporate specific details into the ACO participant agreements.

Response: We will not prescribe additional close-out requirements at this time. However, ACOs may choose to incorporate additional requirements into their ACO participant agreements regarding timing of agreement termination. Additionally, we are pleased that ACOs wish to incorporate additional details related to close-out procedures and intend to make details available through guidance and other operational documents. We encourage, but will not require, ACOs to incorporate these details into their ACO participant agreements once the guidance becomes available.

Comment: A commenter requested that CMS not incorporate proposed language regarding “other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program” into program rules at § 425.204(c)(6) because they believe it would add unnecessary burden.

Response: Under § 425.210(b) of the Shared Savings Program rules, we currently require that contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the Shared Savings Program. This is not a new proposal; however, we have proposed to incorporate this requirement in § 425.204(c)(6). Because this is not a new requirement, and we do not anticipate routinely requesting executed documents, we do not believe it imposes any additional burden on ACOs.

Comment: Some commenters expressed concern that our proposals for ACO participant agreement requirements may lead some readers to conclude that CMS is prohibiting ACO participants from participating in an IPA and in an ACO concurrently. Others

requested reconsideration of the proposed ACO participant agreement requirements and instead permit ‘typical contracts’ between providers and IPAs to qualify. These commenters stated that the proposed regulation would erect a barrier for ACO participation by independent practices that would have to spend time and money reviewing new contracts when they may already have a contract in place that binds them to “all the terms necessary” for ACO participation.

Response: Our example of the requirement for ACOs to have a direct contractual relationship with ACO participants was not intended to suggest that ACO participants may not also have contractual relationships with other entities such as IPAs. We also emphasize that existing IPA contracts we have seen during the application process are insufficient to satisfy the requirements necessary for an ACO participant agreement. For example, typical existing contracts permit IPAs to negotiate with payers on behalf of the independent practice, make no mention of the Shared Savings Program, and do not require independent practices or their practitioners to agree to participate and comply with program rules. Under the Shared Savings Program, payments for services rendered by the independent practices for FFS beneficiaries are not negotiated because such practices continue to bill Medicare for the services the furnish to FFS beneficiaries as they normally would in the absence of the ACO. Additionally, based on previous experience, we believe it is extremely important that each ACO participant and each ACO provider/supplier explicitly understand and acknowledge their participation in the program, how their participation may result in shared savings, their obligations regarding quality reporting, their obligation to comply with all program rules, and other important details of the program. Based on our experience, if ACO participants who are also part of an IPA wish to form an ACO, it is likely that they will have to develop an ACO participant agreement that satisfies the requirements of the Shared Savings Program, and not rely on agreements that have already been executed between the IPA and Medicare-enrolled providers or suppliers for purposes of participating in the IPA.

FINAL ACTION: We will finalize our proposals at § 425.116 for ACO participant and ACO provider/supplier agreement criteria with slight modifications regarding the applicability date. We believe the new regulation will promote a better general

understanding of the Shared Savings Program and transparency for ACO participants and ACO providers/suppliers. We believe that the new requirements regarding agreements between ACOs and ACO participants, together with our earlier guidance regarding good contracting practices, will enhance transparency between the ACO, ACO participants, and ACO professionals, reduce turnover among ACO participants, prevent misunderstandings related to participation in the Shared Savings Program, and assist prospective ACOs in submitting complete applications and requests for adding ACO participants. We believe that codifying these requirements will assist the ACO, ACO participants, and ACO providers/suppliers in better understanding the program and their rights and responsibilities while participating in the program.

In addition, we will finalize our proposal to add at § 425.204(c)(6) a requirement that, as part of the application process and upon request thereafter, the ACO must submit documents demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program, including executed agreements for all ACO participants. Although we will not routinely request an ACO to submit copies of executed agreements the ACO or its ACO participants have with ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities as part of the ACO’s application or continued participation in each performance year, we reserve our right to request this information during the application or renewal process and at any other time for audit or monitoring purposes in accordance with §§ 425.314 and 425.316. Specifically, The ACO is ultimately responsible for ensuring that each ACO provider/supplier billing through the TIN of an ACO participant has agreed to participate in and comply with the Shared Savings Program rules. The ACO can fulfill this obligation either by direction contracting with each ACO provider/supplier (NPI) or contractually requiring the ACO participant to ensure that all ACO providers/suppliers that bill through its TIN have agreed to participate in, and comply with the requirements of, the Shared Savings Program. If the ACO chooses to contract directly with the ACO providers/suppliers, the agreements must meet

virtually the same requirements as the agreements with ACO participants, and the ACO must still have an ACO participant agreement in place with the TIN through which the ACO providers/suppliers bill.

Because of the timing of publication of this final rule, we recognize that ACOs may struggle to incorporate these requirements in time to submit 2016 applications or requests for renewal by the applicable deadlines which will occur during the summer and fall of 2015. While we encourage ACOs to incorporate these requirements into their ACO participant agreements as soon as possible, we will not require these changes to be incorporated into any ACO participant agreements that are submitted to CMS for the 2016 performance year. ACOs that submit requests to add ACO participants for inclusion on the 2017 performance year list of ACO participants will be required to have a corresponding ACO participant agreement that meets the new requirements.

2. Sufficient Number of Primary Care Providers and Beneficiaries

a. Overview

Section 1899(b)(2)(D) of the Act requires participating ACOs to “include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO . . .” and that at a minimum, “the ACO must have at least 5,000 such beneficiaries assigned to it . . .” Under § 425.110(a)(2), an ACO is deemed to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries if the number of Medicare beneficiaries historically assigned to the ACO participants in each of the 3 years before the start of the agreement period is 5,000 or more.

Under the beneficiary assignment methodology set forth in the regulations at part 425, subpart E, the assignment of beneficiaries to a particular ACO for a calendar year is dependent upon a number of factors, including where the beneficiary elected to receive primary care services and whether the beneficiary received primary care services from ACO professionals participating in one or more Shared Savings Program ACOs. We note that to ensure no duplication in shared savings payments for care provided to the same beneficiaries, assignment of a beneficiary may also be dependent on whether the beneficiary has been assigned to another initiative involving shared savings, such as the Pioneer ACO Model (§ 425.114(c)). While a final assignment determination can be made

for the first 2 benchmark years (BY1 and BY2, respectively) for an ACO applying to participate in the Shared Savings Program, it is not possible to determine the final assignment for the third benchmark year (BY3) (that is, the calendar year immediately prior to the start of the agreement period) because application review and determination of whether the ACO has met the required 5,000 assignment must take place during BY3 before all claims are submitted for the calendar year. Furthermore, there is a lag period after the end of a calendar year during which additional claims for the year are billed and processed. Therefore, the final historical benchmark for the 3-year period and the preliminary prospective assignment for PY1 must be determined after the ACO's agreement period has already started. We note that we currently estimate the number of historically assigned beneficiaries for the third benchmark year for Tracks 1 and 2 by using claims with dates of service for the last 3 months of benchmark year 2 (October through December) and the first 9 months of benchmark year 3 (January through September, with up to 3 months claims run out, as available). We use this approach to calculate the number of assigned beneficiaries for BY3 in order to be as consistent as possible with the timeframes (that is, 12 month period) and claims run out used for the BY1 and BY2 calculations.

Section 425.110(b) provides that an ACO that falls below 5,000 assigned beneficiaries at any time during the agreement period will be allowed to continue in the program, but CMS must issue a warning letter and place the ACO on a corrective action plan (CAP). The purpose of this provision is to ensure that the ACO is aware that its number of assigned beneficiaries is below 5,000, is notified of the consequences of remaining under 5,000, and that the ACO is taking appropriate steps to correct the deficiency.

Section 425.110(b)(1) provides that, while under the CAP, the ACO will remain eligible to share in savings for the performance year in which it fell below the 5,000, and the MSR will be adjusted according to the number of assigned beneficiaries determined at the time of reconciliation. For example, according to Table 6 in the November 2011 final rule (42 FR 67928), a Track 1 ACO with an assigned population of 5,000 would have an MSR of 3.9. If the ACO's number of assigned beneficiaries falls below 5,000, we would work with the CMS Office of the Actuary to determine the MSR for the number of beneficiaries below 5,000, set at the

same 90 percent confidence interval that is used to determine an ACO's MSR when the ACO has a smaller assigned beneficiary population. If the number of beneficiaries assigned to the ACO remains less than 5,000 by the end of the next performance year, the ACO is terminated and is not permitted to share in savings for that performance year (§ 425.110(b)(2)).

b. Proposed Revisions

We proposed to revise § 425.110(a)(2) to clarify the data used during the application review process to estimate the number of beneficiaries historically assigned in each of the 3 years of the benchmarking period. Specifically, we proposed that the number of assigned beneficiaries would be calculated for each benchmark year using the assignment methodology set forth in part 425 subpart E, and in the case of BY3, we would use the most recent data available with up to a 3-month claims run out to estimate the number of assigned beneficiaries. This proposed revision would reflect current operational processes under which we assign beneficiaries to ACOs using complete claims data for BY1 and BY2 but must rely on incomplete claims data for BY3. We would continue to estimate the number of historically assigned beneficiaries for the third benchmark year by using claims with dates of service for the last 3 months of BY2 and the first 9 months of BY3, with up to 3 months claims run out. However, that could vary from year to year depending on data availability during the application review process. As discussed previously, we stated our belief that using this approach to calculate the number of assigned beneficiaries for BY3 would be consistent with the timeframes and claims run out used for BY1 and BY2 calculations because we would be using a full 12 months of claims, rather than only the available claims for the calendar year, which would be less than 12 months.

The estimates of the number of assigned beneficiaries would be used during the ACO application review process to determine whether the ACO exceeds the 5,000-assigned beneficiary threshold for each year of the historical benchmark period. We stated that if based upon these estimates, we determined that an ACO had at least 5,000 assigned beneficiaries in each of the benchmark years, it would be deemed to have initially satisfied the eligibility requirement that the ACO have at least 5,000 assigned beneficiaries. The specific data to be used for computing these initial

estimates during the ACO application review process would be designated through program instructions and guidance. Although unlikely, it is possible that when final benchmark year assignment numbers are generated after the ACO has been accepted into the program, the number of assigned beneficiaries could be below 5,000. In this event, we stated that the ACO would be allowed to continue in the program, but may be subject to the actions set forth in § 425.110(b).

Given our experience with the program and the timing of performance year determinations regarding beneficiary assignment provided during reconciliation, we wish to modify our rules to provide greater flexibility to address situations in which an ACO's assigned beneficiary population falls below 5,000 assigned beneficiaries. Specifically, we stated we had concerns that in some cases it may be very difficult for an ACO to increase its number of assigned beneficiaries by the end of the next performance year, as currently required by § 425.110(b)(2). We noted that increasing the number of assigned beneficiaries involves adding new ACO participants and ACO providers/suppliers or both. However, in certain circumstances, by the time the ACO had been notified that its assigned beneficiary population had fallen below 5,000 beneficiaries, it would have been too late for the ACO to add new ACO participants for PY2, leaving the ACO with more limited options for timely correction of the deficit. We stated our belief that § 425.110(b) should be modified to provide ACOs with adequate time to successfully complete a CAP. Therefore, we proposed to revise § 425.110(b)(2) to state that CMS will specify in its request for a CAP the performance year during which the ACO's assigned population must meet or exceed 5,000 beneficiaries. This modification would permit some flexibility for ACOs whose assigned populations fall below 5,000 late in a performance year to take appropriate actions to address the deficit.

Additionally, we stated that we did not believe it would be necessary to request a CAP from every ACO whose assigned beneficiary population falls below 5,000. For example, we stated our belief that we should have the discretion not to impose a CAP when the ACO has already submitted a request to add ACO participants effective at the beginning of the next performance year and CMS has a reasonable expectation that the addition of these new ACO participants would increase the assigned beneficiary population above the 5,000 minimum

beneficiary thresholds. Therefore, we proposed to revise § 425.110(b) to indicate that we have the discretion whether to impose any remedial measures or to terminate an ACO for failure to satisfy the minimum assigned beneficiary threshold. Specifically, we proposed to revise § 425.110(b) to state that the ACO "may" be subject to any of the actions described in § 425.216 (actions prior to termination, including a warning letter or request for CAP) and § 425.218 (termination). However, we noted that although we proposed to retain discretion as to whether to impose remedial measures or terminate an ACO whose assigned beneficiary population falls below 5,000, we recognized that the requirement that an ACO have at least 5,000 assigned beneficiaries is a condition of eligibility to participate in the Shared Savings Program under section 1899(b)(2)(D) of the Act, and would exercise our discretion accordingly and consistently.

Comment: Several commenters commented on our proposal allowing greater flexibility for ACOs who fall below the 5,000 threshold and the CAP. Most commenters supported our proposed modifications, and were supportive of our proposal for CMS to determine the timeframe within which the CAP must be completed when an ACO drops below the 5,000 beneficiary threshold. A commenter supported the proposal but suggested that the calculation of the number of assigned beneficiaries fall "after reconciliation so prospective new members could see actual results." Another commenter supported the proposal for an ACO to avoid a CAP when an ACO has already submitted a request to add ACO participants effective at the beginning of the next performance year and CMS has a reasonable expectation that such addition would increase the assigned beneficiary population above the 5,000 thresholds.

Response: We agree with the comments received in support of a more reasonable timeframe for ACOs to correct a situation whereby the assigned beneficiary population falls below the 5,000 beneficiary threshold. We also agree with the comments received regarding CMS using discretion in issuing a CAP when an ACO has already submitted a request to add ACO participants and CMS has a reasonable expectation that the additional ACO participants will increase the number of beneficiaries above the 5,000 thresholds. We believe that the ACO should be given notification when it falls below 5,000 as soon as possible so that the ACO can take immediate steps to correct the deficit. Therefore, we do not agree

that it would be better to wait until after reconciliation to determine the number of beneficiaries assigned to an ACO or to notify an ACO if it fell below the 5,000 threshold.

Comment: A number of commenters suggested that CMS ensure that ACOs include sufficient number or types of providers, such as pediatricians and geriatricians, to care for the number and the needs of children and elderly managed by the ACO.

Response: As stated in the November 2011 final rule, we do not believe we should be prescriptive in setting any requirements for the number, type, and location of the ACO providers/suppliers that are included in the ACO. Unlike managed care models that require beneficiaries to receive care from a network of providers, beneficiaries assigned to an ACO may receive care from providers and suppliers both inside and outside the ACO. Therefore, we believe that ACOs should have the flexibility to create an organization and design their models in a manner they believe will achieve the three-part aim, and we do not believe it would be useful to announce specific requirements regarding the number, type, and location of ACO providers/suppliers that are included in the ACO.

FINAL ACTION: We are finalizing our proposed policies as proposed related to the requirement that the ACO have at least 5,000 assigned beneficiaries.

We received no comments on our proposed revisions to § 425.110(a)(2) that the number of assigned beneficiaries would be calculated for each benchmark year using the assignment methodology set forth in part 425 subpart E, and in the case of BY3, we will use the most recent data available with up to a 3 month claims run out to estimate the number of assigned beneficiaries. We are finalizing these provisions as proposed.

Given our experience with the program and the timing of performance year determinations regarding beneficiary assignment provided during reconciliation, we are modifying our rules to provide greater flexibility to address situations in which an ACO's assigned beneficiary population falls below 5,000 assigned beneficiaries. Therefore, we are finalizing our proposed revision at § 425.110(b)(2) to state that CMS will specify in its request for a CAP the performance year during which the ACO's assigned population must meet or exceed 5,000 beneficiaries.

Additionally, we are also finalizing our proposed revisions to § 425.110(b) which give CMS discretion regarding whether to impose any remedial measures or to terminate an ACO for

failure to satisfy the minimum assigned beneficiary threshold. However, it is important to note that ACOs must have at least 5,000 assigned beneficiaries as a condition of eligibility to participate in the Shared Savings Program under section 1899(b)(2)(D) of the Act. Therefore we will exercise its discretion accordingly and consistently.

3. Identification and Required Reporting of ACO Participants and ACO Providers/Suppliers

a. Overview

For purposes of the Shared Savings Program, an ACO is an entity that is identified by a TIN and composed of one or more Medicare-enrolled TINs associated with ACO participants (see § 425.20). The Medicare-enrolled TINs of ACO participants, in turn, are associated with Medicare enrolled individuals and entities that bill through the TIN of the ACO participant. (For example, in the case of a physician, the physician has reassigned to the TIN of the ACO participant his or her right to receive Medicare payments, and their services to Medicare beneficiaries are billed by the ACO participant under a billing number assigned to the TIN of the ACO participant).

As part of the application process and annually thereafter, the ACO must submit a certified list identifying all of its ACO participants and their Medicare-enrolled TINs (the "ACO participant list") (§ 425.204(c)(5)(i)). Additionally, for each ACO participant, the ACO must submit a list identifying all ACO providers/suppliers (including their NPIs or other provider identifiers) that bill Medicare during the agreement period under a billing number assigned to the TIN of an ACO participant (the "ACO provider/supplier list") (§ 425.204(c)(5)(i)(A)). Our regulations require the ACO to indicate on the ACO provider/supplier list whether an individual is a primary care physician as defined at § 425.20. All Medicare enrolled individuals and entities that bill through an ACO participant's TIN during the agreement period must be on the certified ACO provider/supplier list and agree to participate in the ACO. ACOs are required to maintain, update, and annually furnish the ACO participant and ACO provider/supplier lists to CMS at the beginning of each performance year and at such other times as may be specified by CMS (§ 425.304(d)).

We use TINs identified on the ACO participant list to identify claims billed to Medicare in order to support the assignment of Medicare fee-for-service beneficiaries to the ACO, the

implementation of quality and other reporting requirements, and the determination of shared savings and losses (see section 1899(b)(2)(E) of the Act). We also use the ACO's initial (and annually updated) ACO participant list to: Identify parties subject to the screenings under § 425.304(b); determine whether the ACO satisfies the requirement to have a minimum of 5,000 assigned beneficiaries; establish the historical benchmark; perform financial calculations associated with quarterly and annual reports; determine preliminary prospective assignment for and during the performance year; determine a sample of beneficiaries for quality reporting; and coordinate participation in the Physician Quality Reporting System (PQRS) under the Shared Savings Program. Both the ACO participant and ACO provider/supplier lists are used to ensure compliance with program requirements. We refer readers to our guidance at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html> for more information.

In this section, we discuss current policy and procedures regarding the identification and required reporting of ACO participants and ACO providers/suppliers. In addition, we proposed revisions to our regulations to improve program transparency by ensuring that all ACO participants and ACO providers/suppliers are accurately identified.

b. Proposed Revisions

In the proposed rule, we stated that in order to administer the Shared Savings Program, we need to accurately identify the ACO participants and ACO providers/suppliers associated with each ACO that participates in the program. An accurate understanding of the ACO participants is critical for assignment of beneficiaries to the ACO as well as assessing the quality of care provided by the ACO to its assigned beneficiaries. An accurate understanding of the ACO providers/suppliers is also critical for ensuring compliance with program rules. We explained our belief that this information is equally critical to the ACO for its own operational and compliance purposes. Thus, both CMS and the ACO need to have a common understanding of the individuals and entities that comprise the ACO participants and ACO providers/suppliers. We obtain this common understanding by requiring the ACO to certify the accuracy of its ACO participant and ACO provider/supplier lists prior to the start of each

performance year and to update the lists as changes occur during the performance year. Because we rely on these lists for both operational and program integrity purposes, we must have a transparent process that results in the accurate identification of all ACO participants and ACO providers/suppliers that compose each ACO in the Shared Savings Program.

We proposed to add a new § 425.118 to reflect with more specificity the requirements for submitting ACO participant and ACO provider/supplier lists and the reporting of changes to those lists. In addition, we proposed to revise § 425.204(c)(5) and to remove § 425.214(a) and § 425.304(d) because these provisions are addressed in new § 425.118.

(1) Certified Lists of ACO Participants and ACO Providers/Suppliers

In the proposed rule, we stated that we intended to continue to require ACOs to maintain, update and submit to CMS accurate and complete ACO participant and ACO provider/supplier lists, but we proposed to establish new § 425.118 to set forth the requirements and processes for maintaining, updating, and submitting the required ACO participant and ACO provider/supplier lists. New § 425.118 would consolidate and revise provisions at § 425.204(c)(5), § 425.214(a) and § 425.304(d) regarding the ACO participant and ACO provider/supplier lists. Specifically, we proposed at § 425.118(a) that prior to the start of the agreement period and before each performance year thereafter, the ACO must provide CMS with a complete and certified list of its ACO participants and their Medicare-enrolled TINs. We would use this ACO participant list to identify the Medicare-enrolled individuals and entities that are affiliated with the ACO participant's TIN in PECOS, the CMS enrollment system. We proposed that all individuals and entities currently billing through the Medicare enrolled TIN identified by the ACO as an ACO participant, must be included on the ACO provider/supplier list. We would provide the ACO with a list of all ACO providers/suppliers (NPIs) that we have identified in PECOS as associated with each ACO participant's Medicare-enrolled TIN. In accordance with § 425.118(a), the ACO would be required to review the list, make any necessary corrections, and certify the lists of all of its ACO participants and ACO providers/suppliers (including their TINs and NPIs) as true, accurate, and complete. In addition, we proposed that an ACO must submit certified ACO participant and ACO provider/supplier

lists at any time upon CMS request. We noted that all NPIs that reassign their right to receive Medicare payment to an ACO participant must be on the certified list of ACO providers/suppliers and must agree to be ACO providers/suppliers. We proposed to clarify this point in regulations text at § 425.118(a)(4).

Finally, in accordance with developing and certifying the ACO participant and provider/supplier lists, we proposed at § 425.118(d) to require the ACO to report changes in ACO participant and ACO provider/supplier enrollment status in PECOS within 30 days after such changes have occurred (for example, to report changes in an ACO provider's/supplier's reassignment of the right to receive Medicare payment or revocation of billing rights). This requirement would correspond with our longstanding policy that requires enrolled providers and suppliers to notify their Medicare Administrative Contractors through PECOS within specified timeframes for certain reportable events. We recognized that PECOS is generally not accessible to ACOs to make these changes directly because most ACOs are not enrolled in Medicare. Therefore, we stated that an ACO may satisfy the requirement to update PECOS throughout the performance year by requiring its ACO participants to submit the required information directly in PECOS within 30 days after the change, provided that the ACO participant actually submits the required information within 30 days. We proposed to require ACOs to include language in their ACO participant agreements (discussed in section II.B.1. of this final rule) to ensure compliance with this requirement. We did not propose to change the current 30-day timeframe required for such reporting in PECOS. These changes would be consistent with the current requirements regarding ACO participant and ACO provider/supplier list updates under § 425.304(d), and we explained our belief that they would enhance transparency and accuracy within the Shared Savings Program. We further proposed to remove § 425.304(d) because the requirements, although not modified, would be incorporated into new § 425.118(d).

In the proposed rule, we stated this revised process should afford the ACO the opportunity to work with its ACO participants to identify its ACO providers/suppliers and to ensure compliance with Shared Savings Program requirements. We also noted that currently, we also require the ACO to indicate whether the ACO provider/supplier is a primary care physician as

defined in § 425.20. Because this information is derived from the claims submitted under the ACO participant's TINs (FQHCs and RHCs being the exception), we stated we found this rule unnecessary to implement the program, so we proposed to remove this requirement, which currently appears in § 425.204(c)(5)(i)(A).

Comment: A few commenters commented on our proposals to establish new § 425.118 to set forth requirements and processes for maintaining, updating, and submitting the required ACO participant and ACO provider/supplier lists. Several commenters agreed with our proposals. A commenter specifically agreed with the proposal but encouraged CMS to consider an extension or transition of the period in which ACOs are required to update their lists, noting that many commercial arrangements permit up to 6 months for ACOs to report relevant changes. A commenter supported the proposal that ACOs must comply with a CMS request for these certified lists contingent that CMS provides a reasonable timeframe in which to comply with such a request. A commenter specifically encouraged CMS to consider an extension or transition of the period in which ACOs are required to update their provider lists. Another commenter stated that CMS should provide ACOs with specific guidance on the process to submit, update, and maintain lists of ACO participants and ACO providers/suppliers as soon as possible to minimize the burden of notification.

Response: The certification of a complete list of ACO participants and their Medicare-enrolled TINs is imperative to ensuring appropriate assignment and ultimately reconciliation for all ACOs. It is important that ACOs take responsibility for maintaining and have the ability to produce these certified ACO participant and ACO provider/supplier lists at any time upon CMS request. We continue to refine the ACO Participant list change process and will inform ACOs about changes to the submission and review process during each performance year. Detailed guidance on this process can be found at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html>. As noted in the guidance, ACOs have several opportunities during the year to make changes that become effective for the next performance year. We therefore believe the timeframe is reasonable for notifying CMS of changes to the list. Furthermore, it is important that ACOs make such changes by the deadline

specified by CMS so that operations such as beneficiary assignment and benchmarking can be completed and communicated to ACOs prior to the next performance year. Therefore, it is not possible to grant an "extension" or "transition" for this due date, unless ACOs are willing to receive benchmarking and assignment information well after the performance year has begun. It is our experience that ACOs prefer to have as much information in advance of a performance year as possible, and so for this reason, we must strictly enforce the due date for changes to the ACO provider list. We believe the deadlines for final notification of changes and certification of the ACO participant list are reasonable because they balance stakeholder desire to notify us as late as possible in the year with stakeholder desire to have beneficiary assignment and benchmarks calculated prior to the next performance year. A longer time period would require either earlier notification of changes or delay information for the next performance year.

Comment: Many commenters supported our proposal to remove the requirement (except for FQHCs and RHCs) to indicate whether an ACO provider/supplier is a primary care physician as defined at § 425.20. Several commenters agreed with our proposal to require the ACO to report changes in ACO participant and ACO provider/suppliers enrollment status in PECOS within 30 days after changes have occurred and to include this requirement in their ACO participant agreements to ensure compliance. A few commenters suggested that CMS incorporate a more reasonable timeframe by which the ACO participants and providers/suppliers must be submitted into PECOS. A commenter requested that CMS provide ACOs with specific guidance on this process as soon as possible and seek to minimize the burden associated with this notification requirement while another comment suggested that an ACO may not be notified and be able to in turn notify CMS of these changes within this same 30-day time period. The time period for the separate notification by the ACO of changes made in the PECOS system by ACO participants and ACO provider/suppliers should be modified to be "within 30 days of ACO learning of such changes from an ACO Participant. Comments received agreed with our proposal that requires ACOs to include language in their ACO participant agreements (discussed in section II.B.1.

of this final rule) to ensure compliance with this requirement.

Response: Transparency and accuracy of the list of ACO participants and ACO providers/suppliers is of the highest importance to the success and integrity of the program. As previously described, it is our longstanding policy to require any changes to an ACO's participants or providers/suppliers be updated in PECOS within 30 days of such addition. This aligns with the Medicare requirement that requires enrolled providers and suppliers to notify their Medicare Administrative Contractors through PECOS within specified timeframes for certain reportable events. ACO participants and ACO providers/suppliers must make these changes; the ACO cannot make the changes directly in PECOS. However, the proposal to require ACOs to include language in their ACO participant agreements (discussed in section II.B.1. of this final rule) to comply with this requirement will strengthen the ACO's ability to educate and direct their ACO participants and ACO providers/suppliers to adhere to this Medicare requirement.

FINAL ACTION: We are finalizing policies as proposed at § 425.118 to set forth the requirements and processes for maintaining, updating, and submitting the required ACO participant and ACO provider/supplier lists.

Specifically, we are finalizing § 425.118(a) that prior to the start of the agreement period and before each performance year thereafter, the ACO must provide CMS with a complete and certified list of its ACO participants and their Medicare-enrolled TINs. All individuals and entities currently billing through the Medicare enrolled TIN identified by the ACO as an ACO participant, must be included on the ACO provider/supplier list. We would provide the ACO with a list of all ACO providers/suppliers (NPIs) that we have identified in PECOS as associated with each ACO participant's Medicare-enrolled TIN. In accordance with § 425.118(a), the ACO would be required to review the list, make any necessary corrections, and certify the lists of all of its ACO participants and ACO providers/suppliers (including their TINs and NPIs) as true, accurate, and complete. In addition, we are also finalizing our proposal at § 425.118 that an ACO must submit certified ACO participant and ACO provider/supplier lists at any time upon CMS request. These changes are consistent with the current requirements regarding ACO participant and ACO provider/supplier list updates under § 425.304(d) which

will be incorporated into new § 425.118(d).

We are also finalizing our proposals at § 425.118(d) to require the ACO to report changes in ACO participant and ACO provider/supplier enrollment status in PECOS within 30 days after such changes have occurred (for example, to report changes in an ACO provider's/supplier's reassignment of the right to receive Medicare payment or revocation of billing rights). This requirement aligns with our longstanding policy that requires enrolled providers and suppliers to notify their Medicare Administrative Contractors through PECOS within specified timeframes for certain reportable events. Therefore, the ACO participant and ACO providers/suppliers must make this change within 30 days, not the ACO itself. However, the ACO is responsible for ensuring the ACO participant or ACO providers/suppliers make the change within the required 30 day time period. We are finalizing our policy to require ACOs to include language in their ACO participant agreements (discussed in section II.B.1. of this final rule) to improve the ability of the ACO to ensure compliance with this requirement.

Finally, we are finalizing the proposal to remove the requirement which currently appears in § 425.204(c)(5)(i)(A) that the ACO indicate primary care physicians on its application to the program.

(2) Managing Changes to ACO Participants

Except for rare instances, such as the cessation of ACO participant operations or exclusion from the Medicare program, we expect ACO participants to remain in the ACO for the entire 3-year agreement period. We believe that care coordination and quality improvement require the commitment of ACO participants. Moreover, as noted previously, we utilize the ACO participant list, among other things, for assigning beneficiaries to the ACO, determining the ACO's benchmark and performance year expenditures, and drawing the sample for ACO quality reporting. We understand that there are legitimate reasons why an ACO may need to update its list of ACO participants during the 3-year agreement period. Thus, under current § 425.214(a), an ACO may add or remove ACO participants (identified by TINs) throughout a performance year, provided that it notifies CMS within 30 days of such addition or removal.

If such changes occur, we may, at our discretion, adjust the ACO's benchmark, risk scores, and preliminary prospective

assignment (§ 425.214(a)(3)). We articulated the timing of these changes in our guidance (<http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html>), which states that we adjust the ACO's historical benchmark at the start of a performance year if the ACO participant list that the ACO certified at the start of that performance year differs from the one it certified at the start of the prior performance year. We use the updated certified ACO participant list to assign beneficiaries to the ACO in the benchmark period (the 3 years prior to the start of the ACO's agreement period) in order to determine the ACO's adjusted historical benchmark. Our guidance provides that, as a result of changes to the ACO's certified ACO participant list, we may adjust the historical benchmark upward or downward. We use the new annually certified list of ACO participants and the adjusted benchmark for the following program operations: The new performance year's assignment; quality measurement and sampling; reports for the new performance year; and financial reconciliation. We provide ACOs with the adjusted Historical Benchmark Report reflecting these changes.

However, our guidance stated that absent unusual circumstances, changes in ACO participants that occur in the middle of a performance year will not result in midyear changes to assignment, sampling for quality reporting, financial reconciliation, or other matters.

As indicated in our guidance, the midyear removal of an entity from the ACO participant list due to program integrity issues is one unusual circumstance that could result in midyear changes to assignment and other matters. Finally, our guidance states that we do not make adjustments upon Medicare payment changes such as wage-index adjustments, or the addition or deletion of ACO participants during the course of the performance year made by the ACO and ACO participants.

We proposed to add new provisions at § 425.118(b) to address the procedures for adding and removing ACO participants during the agreement period. These proposals would revise the regulations to incorporate some of the important policies that we have implemented through our operational guidance as well as some additional proposals to ease the administrative burden generated by the magnitude of changes made to ACO participant lists to date.

We proposed under § 425.118(b)(1) that an ACO must submit a request to add a new entity to its ACO participant list in the form and manner specified by CMS and that CMS must approve additions to the ACO participant list before they can become effective. We stated our belief that ACO participants should be admitted into the program if, for example, the screening conducted under § 425.304(b) reveals that the entity has a history of program integrity issues, or if the ACO participant agreement with the entity does not comply with program requirements, or if the entity is participating in another Medicare shared savings initiative (§ 425.114). If CMS denies the request to add an entity to the ACO participant list, then the entity would not be eligible to participate in the ACO for the upcoming performance year.

We proposed that, if CMS approves the request, the entity would be added to the ACO participant list at the beginning of the following performance year. That is, entities that are approved for addition to the ACO participant list would not become ACO participants, and their claims would not be considered for purposes of benchmarking, assignment and other operational purposes, until the beginning of the next performance year. For example, if an ACO notifies CMS of the addition of an entity in June of the second performance year (PY2), the entity would not become an ACO participant and its claims would not be included in program operations until January 1 of PY3 if CMS approves the entity's addition.

We proposed that an ACO must notify CMS no later than 30 days after the date of termination of the entity's ACO participant agreement, although the ACO may notify CMS in advance of such termination. We proposed that the ACO must submit the notice of removal, which must include the date of termination, in the form and manner specified by CMS. We proposed that the removal of the ACO participant from the ACO participant list would be effective on the date of termination of the ACO participant agreement.

We proposed at § 425.118(b)(3)(i) that changes made by an ACO to its annually certified ACO participant list would result in adjustments to its historical benchmark, assignment, quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals for certain CMS quality initiatives. We would annually adjust the ACO's benchmark calculations to include (or exclude) the claims submitted during the benchmark years by the newly added (or removed) ACO

participants. In other words, the annually certified ACO participant list would be used for purposes of subparts E (assignment of beneficiaries), F (quality performance assessment), and G (calculation of shared savings/losses) for the performance year. For example, if an ACO began program participation in 2013, the PY1 certified list would be used to generate an historical benchmark calculated from claims submitted by the TINs on the PY1 certified list during CY 2010, 2011, and 2012. If the ACO adds ACO participants during 2013 and certifies an updated list for PY2 reflecting those additions, we would adjust the historical benchmark to accommodate those changes by recalculating the benchmark using the claims submitted by the PY2 list of certified ACO participants during the ACO's same benchmark years (CYs 2010, 2011, and 2012). In this way, the ACO's benchmark would continue to be based on the same 3 years prior to the start of the ACO's agreement, but our proposal would ensure that the changes in ACO composition and performance year calculations retain a consistent comparison between benchmark and performance during the agreement period.

As noted previously, adjustment to the ACO's historical benchmark as a result of changes to the ACO's certified ACO participant list may move the benchmark upward or downward. We would use the annual certified ACO participant list and the adjusted benchmark for the new performance year's beneficiary assignment, quality measurement and other operations that are dependent on the ACO participant list as outlined in our guidance. We would provide ACOs with an adjusted Historical Benchmark Report that reflects the new certified ACO participant list. We proposed to add this requirement at § 425.118(b)(3).

We proposed at § 425.118(b)(3)(ii) to codify the policy we established in guidance that, absent unusual circumstances, the removal of an ACO participant from the ACO participant list during the performance year must not affect certain program calculations for the remainder of the performance year in which the removal becomes effective. Namely, the removal of an entity from the ACO participant list during the performance year would not affect the ACO's beneficiary assignment or, by extension, such program operations as the calculation of the ACO's historical benchmark, financial calculations for quarterly and annual reporting, the sample of beneficiaries for quality reporting, or the obligation of the ACO to report on behalf of eligible

professionals for certain quality initiatives. In other words, absent unusual circumstances, CMS would use only the ACO participant list that is certified at the beginning of a performance year to assign beneficiaries to the ACO under subpart E and to determine the ACO's quality and financial performance for that performance year under subparts F and G. We gave examples of unusual circumstances that might justify midyear changes, including the midyear removal of an ACO participant due to evidence of avoidance of at-risk beneficiaries or other program integrity issues.

For example, if an ACO participant is on the ACO's certified list of ACO participants for the second performance year, and the ACO timely notifies CMS of the termination of the entity's ACO participant agreement effective June 30th of PY2, the ACO participant would be removed from the ACO participant list effective June 30th of PY2. However, the former ACO participant's TIN would still be used for purposes of calculating the quality reporting requirements, financial reports, benchmarking, assignment and reporting of PQRS, meaningful use of EHR, and the value-based modifier. The ACO participant list that was certified at the start of the performance year governs the assessment of the ACO's financial and quality performance for that year, regardless of changes to the list during the performance year. We explained our belief that this is necessary to help create some stability in the assessment of the ACO's quality and financial performance for each performance year. If CMS had to modify underlying program operations each time an ACO added or removed a TIN from its list of ACO participants, the ACO would not be able to rely on information (such as the calculation of the historical benchmark) that we provide before the beginning of the performance year.

We stated our belief that it is important for ACOs to communicate effectively with ACO participants that seek to join an ACO so that they understand the potential impact to the ACO, the ACO participant, and the ACO providers/suppliers affiliated with the ACO participant when an ACO participant leaves during a performance year. For example, it is likely that the ACO would be required to report quality data for beneficiaries that were seen by the former ACO participant in the previous 12 months. The ACO must work with the former ACO participant to obtain the necessary quality reporting data. Additionally, the ACO participant would not be able to qualify for PQRS

incentive payment or avoid the PQRS payment adjustment separately from the ACO for that performance year.

Therefore, we stated that it is in the best interest of both parties to understand this in advance and to commit to working together to fulfill the obligations for the performance year. To assist ACO and ACO participants, we proposed criteria for ACO participant agreements addressing this issue (see section II.B.1. of this final rule).

Comment: Many commenters supported our proposals related to adding and removing an ACO participant TIN midyear and having these added TINs become effective for the benchmark, assignment, and other operational processes on January 1 of the following year of the agreement period. A few commenters encouraged CMS to allow participant TINs to be added at any point in the agreement period and to be automatically reflected in a ACOs benchmarking and assignment. A few commenters recommended that CMS only alter the ACO's benchmark, risk score, and assignment if there is a substantial change to the ACO participant list. Others commenters supported the proposal to limit removal of ACO participants to once a year, except in the event of a compliance issue or business failure.

Response: As noted, these proposals are consistent with current operational guidance. Given the high number of requests for modification to ACO participant lists, we believe these policies are necessary to create stability in the assessment of ACOs. It is not feasible to modify underlying program operations each time an ACO adds or removes a TIN from its list of ACO participants. If we were to do this, the ACO would have unwanted midyear fluctuations in the preliminary prospectively assigned beneficiary population, benchmark, and quality sample. Given that we are finalizing other proposed changes in other sections of this rule in response to ACO requests for stability in operations, permitting midyear changes in TINs that affect operations during the performance year would be counterproductive. However, not making such modifications at the beginning of each performance year to account for changes to the ACO participant list could create disparities between the benchmark and performance year financial calculations, either disproportionately advantaging or disadvantaging the ACO. Additionally, because there is no uniformity in the number of ACO providers/suppliers that bill through the TIN of an ACO

participant, we will not adjust benchmarks to account only for substantial changes to the ACO participant list. Therefore, we are finalizing our proposal to update the ACO's assignment and benchmark at the start of each new performance year to reflect modifications that the ACO makes to its certified list of ACO participants. We believe this policy is both fair and reduces the opportunity for gaming.

Comment: A commenter noted that the requirement for ACO participants that are removed during a performance year to continue to assist the ACO with quality reporting, sometimes months after leaving the ACO, can create problems for ACO quality data collection.

Response: As previously discussed, we believe it is important for ACOs to transparently communicate expectations to prospective ACO participants and that both the ACO and its ACO participants make a commitment to the 3-year agreement. In this way, there will be no misunderstandings regarding required close-out procedures, including required quality reporting. To assist the ACO in this regard, we are finalizing certain requirements for ACO participant agreements as discussed in section II.B.1 of this final rule, including the obligation of the ACO participant and ACO to complete close-out procedures which include quality reporting requirements.

Comment: Some commenters requested that ACOs be allowed to add participants any time during a performance year up until November 30th while others objected to having to certify ACO participant lists prior to January 1 of the next performance year. Another commenter, disagreed with the requirement that an ACO participant TIN be screened and approved for participation by CMS before being added to the ACO participant list, stating this adds burden for the ACO.

Response: Timelines for final submission of changes to the ACO participant list at the end of a performance year are established in order to properly screen, obtain certified lists for the new performance year, and determine new benchmarks and assignments for the new performance year. Delaying these timelines would result in delays of issuance of new performance year information for the ACO. We will continue to evaluate this issue and our timelines to ensure the best balance between the timing of end of year changes and creation of information for the ACO's next performance year. Finally, to protect the integrity of the Shared Savings Program,

we must screen all ACO participant TINs that are added during a performance year without exception. Such screening takes time, although it is done as quickly as possible, but we do not agree that this necessity imposes undue burden for ACOs.

FINAL ACTION: We are finalizing our proposals at § 425.118(b) related to changes in the ACO participant list. Specifically, we are finalizing our proposal under § 425.118(b)(1) that an ACO must submit a request to add a new entity to its ACO participant list in the form and manner specified by CMS and that CMS must approve additions to the ACO participant list before they can become effective on January 1 of the following performance year. We are also finalizing our proposal at § 425.118(b)(2) that an ACO must notify CMS no later than 30 days after the termination of an ACO participant agreement and that the notice must be submitted in the form and manner specified by CMS and must include the date of the termination date of the ACO participant agreement. The entity will be deleted from the ACO participant list as of the termination date of the ACO participant agreement. Finally, we are finalizing our proposal at § 425.118(b)(3)(i) that any changes made by an ACO to its annually certified ACO participant list would result in adjustments to its historical benchmark, assignment, quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals for certain CMS quality initiatives. Additionally, absent any public comment and for the reasons noted in the proposed rule, we are finalizing our proposal at § 425.118(b)(3)(ii) to codify the policy we established in guidance that, absent unusual circumstances, the removal of an ACO participant from the ACO participant list during the performance year must not affect certain program calculations for the remainder of the performance year in which the removal becomes effective. However, we are making a minor revision to the text of the provisions at both § 425.118(b)(3)(i) and § 425.118(b)(3)(ii) to replace the references to ACO providers/suppliers with a reference to "eligible professionals that bill under the TIN of an ACO participant." We believe this change is necessary to clarify that the requirement that the ACO report on behalf of these eligible professionals applies even if they are not included on the ACO provider/supplier list. For example, an ACO must still report quality data for services billed under the TIN of an ACO participant by an eligible professional that was an ACO provider/

supplier for a portion of the performance year but was removed from the ACO provider/supplier list midyear when he or she started a new job and ceased billing under the TIN of the ACO participant.

(3) Managing Changes to ACO Providers/Suppliers

We recognize that ACO providers/suppliers may terminate their affiliation with an ACO participant or affiliate with new or additional Medicare-enrolled TINs (which may or may not be ACO participants) on a frequent basis. Thus, the annual certified ACO provider/supplier list may quickly become outdated. In order to ensure that CMS and the ACO have a common understanding of which NPIs are part of the ACO at any particular point in time, our regulations at § 425.214 set forth requirements for managing changes to the ACO during the term of the participation agreement. Specifically, §§ 425.214(a)(2) and 425.304(d)(2) require an ACO to notify CMS within 30 days of the addition or removal of an ACO provider/supplier from the ACO provider/supplier list.

We proposed new § 425.118(c) on how to report changes to the ACO provider/supplier list that occur during the performance year. Under proposed § 425.118(c), ACOs would continue to be required to report these changes within 30 days. As discussed later in this section, we would require the ACO to ensure that changes in ACO participant and ACO provider/supplier enrollment status are reported in PECOS. However, because the lists of ACO providers/suppliers cannot be maintained in PECOS, we proposed to require ACOs to notify CMS' Shared Savings Program separately, in the form and manner specified by CMS, of the addition or removal of an ACO provider/supplier. In the proposed rule, we stated our expectation that ACOs would be required to send such notifications via electronic mail and that specific guidance regarding this notification process would be provided by the Secretary on the CMS Web site and through the ACO intranet portal or both.

We proposed that an ACO may add an individual or entity to the ACO provider/supplier list if it notifies CMS within 30 days after the individual or entity became a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. We proposed that if the ACO provided such notice by the 30-day deadline, the addition of an ACO

provider/supplier would be effective on the date specified in the notice furnished to CMS but no earlier than 30 days before the date of notice. If the ACO failed to provide timely notice to CMS regarding the addition of an individual or entity to the ACO provider/supplier list, then the addition would become effective on the date CMS receives notice from the ACO. However, we noted that when an individual has begun billing through the TIN of an ACO participant but is not on the ACO provider/supplier list, the individual would satisfy the definition of "ACO professional," in which case his or her claims for services furnished to Medicare fee-for-service beneficiaries would be considered for assignment and other operational purposes previously described.

Each potential ACO provider/supplier that reassigns his or her billing rights under the TIN of an ACO participant is screened by CMS through the enrollment process and PECOS system. Additionally, the Shared Savings Program conducts additional screening on a biannual basis for each ACO provider/supplier through the CMS Fraud Prevention System. In spite of this, we stated our concern that the proposed effective date for the addition of an individual or entity to the ACO provider/supplier list would prevent us from conducting a robust program integrity screening of such individuals and entities. Therefore, we considered whether to delay the effective date of any additions to the ACO provider/supplier list until after we have completed a program integrity screening of the individuals or entities that the ACO wishes to add to the list. For example, we considered whether to delay the effective date of additions to the ACO provider/supplier list until the start of the next performance year, similar to the timing for adding TINs of ACO participants to the list of ACO participants. In this way, a complete yearly screening, including screening for program integrity issues, could occur at one time for both the ACO participant list and the ACO provider/supplier list. As previously noted, until the individual or entity has been officially designated as an ACO provider/supplier, that individual or entity would be an ACO professional because of its billing relationship with the ACO participant. Thus, any claims billed by the ACO professional through the TIN of the ACO participant would be used for assignment and related activities during the performance year in which the change takes place, regardless of whether the individual or entity

subsequently becomes an ACO provider/supplier. We sought comment on this proposal.

We proposed to remove an ACO provider/supplier from the ACO provider/supplier list, an ACO must notify CMS no later than 30 days after the individual or entity ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The individual or entity would be removed from the ACO provider/supplier list effective as of the date the individual or entity terminates its affiliation with the ACO participant.

Comment: A few commenters commented on our proposed addition at § 425.118(c) regarding requirements for changes to the ACO provider/supplier list and were in agreement with our proposals. A commenter expressed concern about the time frames, specifically having to receive notification from the ACO provider/supplier and then notifying CMS within the required 30 days of such a change. In addition, this commenter suggested the regulations be modified to require notification to CMS within 30 days of notification to the ACO by the ACO participant.

Response: We appreciate the support for these proposals and will finalize them as proposed. We believe the requirement for an ACO to notify CMS within 30 days of a change is appropriate because it is consistent with PECOS enrollment requirements and current program rules. We note that if the ACO provider/supplier is not formally added to the ACO's list of ACO providers/suppliers, the individual billing through the TIN of an ACO participant would be an ACO professional and as such, his or her claims would be included in operations related to such things as beneficiary assignment during the performance year in which the entity begins billing. However, the ACO must develop internal processes to identify such entities to comply with program rules.

FINAL ACTION: We are finalizing our proposals at § 425.118(c) as proposed for managing changes to ACO providers/suppliers.

Specifically, we are finalizing our proposal that an ACO must notify CMS within 30 days after the individual or entity becomes a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The addition of an ACO provider/supplier would be

effective on the date specified in the notice furnished to CMS but no earlier than 30 days before the date of notice. Additionally, we are finalizing our proposal that an ACO must notify CMS no later than 30 days after the individual or entity ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The removal of an individual or entity from the ACO provider/supplier list is effective as of the date the individual or entity ceases to be a Medicare-enrolled provider or supplier that bills for items and services furnished to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of the ACO participant. Notices must be submitted in the form and manner specified by CMS.

(4) Update of Medicare Enrollment Information

We proposed at § 425.118(d) to require the ACO to ensure that changes in ACO participant and ACO provider/supplier enrollment status are reported in PECOS consistent with § 424.516 (for example, changes in an ACO provider's/supplier's reassignment of the right to receive Medicare payment or revocation of billing rights). As previously discussed in detail, this proposed requirement would correspond with our longstanding policy that requires enrolled providers and suppliers to notify their Medicare Administrative Contractors through PECOS within specified timeframes for certain reportable events.

Comment: A commenter requested that we not finalize the proposed requirement because ACOs cannot ensure that third parties will report changes in PECOS and ACOs do not have the legal authority to enforce this requirement. Another commenter suggested that CMS provide ACOs with specific guidance on this process as soon as possible to minimize burden associated with the notification requirement.

Response: We believe it is important that the ACO ensure that changes in ACO participant and ACO provider/supplier enrollment status are reported in PECOS consistent with current Medicare rules at § 424.516. This requirement ensures that both the ACO and CMS have a complete and accurate understanding of precisely which individuals and entities are treating Medicare beneficiaries in the Shared Savings Program and are therefore subject to the requirements of part 425.

Under new § 425.116, ACO participant and ACO provider/supplier agreements must require the ACO participant and ACO provider/supplier to update enrollment information in a timely manner and to notify the ACO of such changes within 30 days. Thus, through its agreements with ACO participants and ACO providers/suppliers, ACOs will have the ability to require timely reporting of enrollment changes and to enforce this requirement.

FINAL ACTION: We are finalizing our proposal at § 425.118(d) to require the ACO to ensure that changes in ACO participant and ACO provider/supplier enrollment status are reported in PECOS consistent with § 424.516 (for example, changes in an ACO provider's/supplier's reassignment of the right to receive Medicare payment or revocation of billing rights).

4. Significant Changes to an ACO

a. Overview

Section 425.214(b) requires an ACO to notify CMS within 30 days of any significant change. A significant change occurs when an ACO is no longer able to meet the Shared Savings Program eligibility or program requirements (§ 425.214(b)). Upon receiving an ACO's notice of a significant change, CMS reviews the ACO's eligibility to continue participating in the Shared Savings Program and, if necessary, may terminate the ACO's participation agreement (§ 425.214 (c)). In addition, § 425.214(c)(2) provides that CMS may determine that a significant change has caused the ACO's structure to be so different from what was approved in the ACO's initial application that it is no longer able to meet the eligibility or program requirements. Under such circumstances, CMS would terminate the ACO's participation agreement, and permit the ACO to submit a new application for program participation. In the November 2011 final rule (76 FR 67840), we noted that changes to an ACO participant list could constitute a significant change to an ACO if, for example, the removal of a large primary care practice from the list of ACO participants caused the number of assigned beneficiaries to fall below 5,000.

b. Proposed Revisions

In light of changes proposed in the section II.B.3. of this final rule, we proposed to redesignate § 425.214(b) and (c) as § 425.214(a) and (b). Second, we proposed to describe when certain changes to the ACO constitute a significant change to the ACO. We believe that a change in ownership of an

ACO or the addition or deletion of ACO participants could affect an ACO's compliance with the governance requirements in § 425.106 or other eligibility requirements. We noted that some changes to the ACO participant list may be of such a magnitude that the ACO is no longer the same entity as when it was originally approved for program participation. In addition, depending on the nature of the change in ownership, the ACO would need to execute a new participation agreement with CMS if the existing participation agreement is no longer with the correct legal entity. We stated that such changes would constitute significant changes and should be subject to the actions outlined under § 425.214(b). Therefore, we proposed to specify at § 425.214(a) that a significant change occurs when the ACO is no longer able to meet the eligibility or other requirements of the Shared Savings Program, or when the number or identity of ACO participants included on the ACO participant list, as updated in accordance with § 425.118, changes by 50 percent or more during an agreement period. For example, in the case of an ACO whose initial certified ACO participant list contained 10 ACO participants, five of which gradually left the ACO and either were not replaced or were replaced with five different ACO participants, the ACO would have undergone a significant change because the number or identity of its ACO participants changed by 50 percent. Similarly, if an ACO's initial certified ACO participant list contains 20 ACO participants, and the ACO incrementally adds 10 new ACO participants for a total of 30 ACO participants, it would have undergone a significant change with the addition of the 10th new ACO participant.

Upon notice from an ACO that experienced a significant change, we would evaluate the ACO's eligibility to continue participating in the Shared Savings Program and make one of the determinations listed in the provision we proposed to redesignate as § 425.214(b). We may request additional information to determine whether and under what terms the ACO may continue in the program. We noted that a determination that a significant change has occurred would not necessarily result in the termination of the ACO's participation agreement. We proposed to modify § 425.214 to provide that an ACO's failure to notify CMS of a significant change must not preclude CMS from determining that the ACO has experienced a significant change.

In addition, we sought comment on whether we should consider amending our regulations to clarify that the ACO

must provide notice of a significant change prior to the occurrence of the significant change. We believe some significant changes could require a longer notice period, particularly in the case of a change of ownership that causes the ACO to be unable to comply with program requirements. Therefore, we sought comment on whether ACOs should be required to provide 45 or 60 days' advance notice of a significant change. We also sought comment on what changes in the ACO participant list should constitute a significant change.

Comment: Many commenters agreed with our proposals which specify at § 425.214(a) that a significant change occurs when the ACO is no longer able to meet the eligibility or other requirements of the Shared Savings Program, or when the number or identity of ACO participants included on the ACO participant list, as updated in accordance with § 425.118, changes by 50 percent or more during an agreement period. However, we received several comments from stakeholders that opposed or questioned how a change in ACO participant TINs might represent a significant change. Several commenters stated that a simple 50 percent threshold does not necessarily identify a major change and recommended that CMS take into consideration that a 50 percent change for a small ACO could be the turnover a very small number of TINs. Commenters suggested an alternative approach that looks at a percentage change in ACO providers/suppliers or assigned beneficiaries as opposed to changes in ACO participant TINs. A commenter noted that changes in ACO participant TINs should not be confused with the ability of the ACO to meet eligibility requirements.

Response: At the inception of the program, we did not anticipate that ACOs would make changes to ACO participant TINs to the extent they have because program rules require the ACO and its ACO participants to make a commitment to the 3-year participation agreement according to § 425.306(a). Such changes raise concerns that are unrelated to the ability of an ACO to meet eligibility requirements, such as gaming or the ability of the ACO participants to develop and adhere to the care coordination processes established by the ACO that are necessary to succeed in the ACO's goals of improving quality and reducing growth in costs for its assigned population. However, although we still have reservations about ACOs that have dramatic ACO participant list changes, we understand that the use of the 50

percent measure may not be the best mechanism for determining whether an ACO has undergone a significant change. Therefore at this time we will not finalize the proposed change that would designate an ACO as undergoing a significant change if its ACO participant list changes by 50 percent or more during an agreement period. However, we intend to monitor such changes and may audit and request additional information from ACOs that undergo changes in their list of ACO participant TINs over the course of the agreement period in order to better understand the implications and impacts of such changes. We may revisit this issue in future rulemaking, pending additional experience with the program.

Comment: A number of commenters noted it is not always possible for an ACO to provide advance notice of a significant change because some changes may not actually come to fruition or may happen on a tight schedule. These commenters suggested that, if finalized, advanced notice of a significant change should only be required when possible or on a case-by-case basis. A commenter stated that CMS should give ACOs a minimum of 45 days advance notice when the ACO has undergone a significant change to permit sufficient time for the ACO to make appropriate modifications.

Response: We thank stakeholders for responding to our request for comment on whether we should consider amending our regulations to clarify that the ACO must provide notice of a significant change prior to the occurrence of the significant change. At this time, we will continue to require ACOs to notify us within 30 days after the occurrence of a significant change. Because it may not be possible to provide sufficient advance notice of a significant change, we will not require ACOs to give us advanced notice of such events, but we strongly encourage ACOs to alert us in advance when, for example, significant organizational changes occur or are likely to occur that may impact the ability of the ACO to continue to meet eligibility requirements. Notifying us in advance of such changes gives us the opportunity to work with the ACO to ensure compliance and avoid unanticipated operational pitfalls for the ACO. Similarly, if we become aware of a significant change that has occurred to an ACO, we will alert the ACO as soon as possible and indicate the timeframe in which it is necessary for the ACO to comply.

FINAL ACTION: We are finalizing our proposal to redesignate § 425.214(b) and (c) as § 425.214(a) and (b). We are also

finalizing our proposal to modify § 425.214 to continue to require an ACO to alert us when a significant change occurs and to provide that an ACO's failure to notify CMS of a significant change does not preclude CMS from determining that the ACO has experienced a significant change. Finally, based on comments, we are not finalizing our proposal to specify at § 425.214(a) that a significant change occurs when the number or identity of ACO participants included on the ACO participant list, as updated in accordance with § 425.118, changes by 50 percent or more during an agreement period. However, we will continue to monitor this issue and may audit or otherwise request information from ACOs with changes to the ACO participant list during the agreement period. Although we are not at this time requiring advanced notice of significant changes, we believe that it is in the best interest of the ACO to contact us in advance if it believes that an organizational change, such as a change in ownership, may occur so that we can work with the ACO to ensure continued compliance and avoid operational pitfalls.

5. Consideration of Claims Billed by Merged/Acquired Medicare-Enrolled Entities

a. Overview

As discussed in the November 2011 final rule (76 FR 67843), we do not believe that mergers and acquisitions by ACO providers and suppliers are the only way for an entity to become an ACO. The statute and our regulations permit ACO participants that form an ACO to use a variety of collaborative organizational structures, including collaborations other than merger. We reject the proposition that an entity under single control, that is, an entity formed through a merger, would be more likely to meet the goals of improved health at a lower cost. However, we have received questions from industry stakeholders regarding how previous mergers and acquisitions of entities with Medicare enrolled billing TINs will be treated for purposes of the Shared Savings Program. In particular, some applicants have inquired whether the claims billed to Medicare in previous years by an entity that has since been merged with, or acquired by, a different entity could be used to determine whether an applicant meets the requirement to have at least 5,000 beneficiaries assigned to it in each of the benchmark years (§ 425.110) and to establish the ACO's historical benchmark and preliminary prospective

assignment. To illustrate, suppose a large group practice that is a prospective ACO participant recently purchased two small primary care practices, and the primary care practitioners from those small practices have reassigned the right to receive Medicare payment to the larger group practice Medicare-enrolled TIN. In this instance, it is likely that the primary care providers will continue to serve the same patient population they served before the practices were purchased, and that their patients may appear on the ACO's list of assigned beneficiaries at the end of the performance year. Therefore, applicants and established ACOs have inquired whether there is a way to take into account the claims billed by the Medicare-enrolled TINs of practices acquired by sale or merger for purposes of meeting the minimum assigned beneficiary threshold and creating a more accurate benchmark and preliminary prospective list of assigned beneficiaries for the upcoming performance year. Similarly, an established ACO may request consideration of the claims billed by the Medicare-enrolled TINs of entities acquired during the course of a performance year for the same purposes.

In response to questions from industry stakeholders, we provided additional guidance on our Web site to all Shared Savings Program applicants about the requirements related to mergers and acquisitions (see <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/Merger-Acquisitions-FAQ.pdf>). In this guidance, we indicated that under the following circumstances, we may take the claims billed under TINs of entities acquired through purchase or merger into account for purposes of beneficiary assignment and the ACO's historical benchmark:

- The ACO participant must have subsumed the acquired entity's TIN in its entirety, including all the providers and suppliers that reassigned the right to receive Medicare payment to that acquired entity's TIN.
- All the providers and suppliers that previously reassigned the right to receive Medicare payment to the acquired entity's TIN must reassign that right to the TIN of the acquiring ACO participant.

• The acquired entity's TIN must no longer be used to bill Medicare.

In order to attribute the billings of merged or acquired TINs to the ACO's benchmark, the ACO applicant must—

- Submit the acquired entity's TIN on the ACO participant list, along with an attestation stating that all providers and

suppliers that previously billed under the acquired entity's TIN have reassigned their right to receive Medicare payment to an ACO participant's TIN;

- Indicate the acquired entity's TIN and which ACO participant acquired it; and

- Submit supporting documentation demonstrating that the entity's TIN was acquired by an ACO participant through a sale or merger and submit a letter attesting that the acquired entity's TIN will no longer be used to bill Medicare.

We noted in the proposed rule that we require an applicant's list of ACO providers/suppliers to include all individuals who previously billed under the acquired entity's TIN to have reassigned their right to receive Medicare payment to an ACO participant's TIN.

We stated that the policies set forth in our guidance were necessary to ensure that these entities have actually been completely merged or acquired and that it would be likely that the primary care providers will continue to serve the same patient population. In this way, the beneficiary assignments and the benchmarks would be more accurate for ACOs that include merged or acquired Medicare-enrolled TINs under which their ACO professionals billed during application or updates to the ACO participant list.

b. Proposed Changes

In the proposed rule, we stated that current guidance and processes are working well and benefit both CMS (for example, by providing assurance that an entity's Medicare-enrolled billing TIN have actually been acquired through sale or merger) and the affected ACOs (for example, by allowing for an increase in the ACO's number of appropriately assigned beneficiaries and providing for a more accurate financial benchmark). To avoid uncertainty and to establish a clear and consistent process for the recognition of the claims previously billed by the TINs of acquired entities, we proposed to codify the current operational guidance on this topic at § 425.204(g) with some minor revisions to more precisely and accurately describe our proposed policy. Proposed § 425.204(g) would add the option for ACOs to request consideration of claims submitted by the Medicare-enrolled TINs of acquired entities as part of their application, and would address the documentation requirements for such requests. We noted that although this provision is added in § 425.204 regarding the content of the initial application, we proposed to permit ACOs to annually

request consideration of claims submitted by the TINs of entities acquired through sale or merger upon submission of the ACO's updated list of ACO participants.

Comment: All commenters supported our proposal to allow ACOs to request consideration of claims submitted by the Medicare-enrolled TINs of acquired entities as part of their application and to permit ACOs to annually request consideration of claims submitted by the TINs of entities acquired through sale or merger upon submission of the ACO's updated list of ACO participants. A commenter encouraged CMS to provide as much flexibility as possible to take the billings of merged or acquired TINs into account because the ACO marketplace may undergo significant changes in the future (for example, mergers and acquisitions of ACOs).

Response: We appreciate the comments supporting our proposals. We agree that finalizing these proposals will establish a clear and consistent process for the recognition of the claims previously billed by the TINs of acquired entities. We believe we are providing as much flexibility as possible at this time, although we are open to considering additional flexibilities in future rulemaking. We invite stakeholders to let us know what specific additional flexibilities may be warranted in the future.

FINAL ACTION: We are finalizing our proposal to codify the current operational guidance on consideration of claims billed by merged or acquired TINs at § 425.204(g), including our proposals for minor revisions to more precisely and accurately describe our policy. Specifically, we are finalizing the proposal at § 425.204(g) to add the option for ACOs to request consideration of claims submitted by the Medicare-enrolled TINs of acquired entities as part of their application, and address the documentation requirements for such requests. We are finalizing at § 425.118(a)(2) our proposal to permit ACOs to annually request consideration of claims submitted by the TINs of entities acquired through sale or merger upon submission of the ACO's updated list of ACO participants. Specifically, § 425.118(a)(2) provides that such requests may be made in accordance with the process set forth at § 425.204(g). More detailed information on the manner, format, and timelines for ACOs to submit such requests will be found in operational documents and guidance.

6. Legal Structure and Governance

Section 1899(b)(1) of the Act requires ACO participants to have established a “mechanism for shared governance” in order to be eligible to participate as ACOs in the Shared Savings Program. In addition, section 1899(b)(2)(C) of the Act requires the ACO to have a formal legal structure that allows the organization to receive and distribute shared savings payments to ACO participants and ACO providers/suppliers. We believe the formal legal structure should be designed and implemented to protect against conflicts of interest or other improper influence that may otherwise arise from the receipt and distribution of payments or other ACO activities. We proposed clarifications to our rules related to the ACO’s legal entity and governing body. The purpose of these proposed changes was to clarify our regulations and to ensure that ACO decision-making is governed by individuals who have a fiduciary duty, including a duty of loyalty, to the ACO alone and not to any other individuals or entities. We believe the proposed changes are relatively minor and would not significantly impact the program as currently implemented.

a. Legal Entity and Governing Body

(1) Overview

As specified in the November 2011 final rule (76 FR 67816) and at § 425.104(a), an ACO must be a legal entity, formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates for the following purposes:

- Receiving and distributing shared savings.
- Repaying shared losses or other monies determined to be owed to CMS.
- Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.
- Fulfilling other ACO functions identified in this part.

Additionally, under § 425.104(b), an ACO formed by two or more “otherwise independent” ACO participants must be a legal entity separate from any of its ACO participants. Our regulations at § 425.106(b)(4) further specify that when an ACO comprises “multiple, otherwise independent ACO participants,” the governing body of the ACO must be “separate and unique to the ACO.” In contrast, if the ACO is an “existing legal entity,” the ACO governing body may be the same as the governing body of that existing legal entity, provided it satisfies all other requirements of § 425.106, including provisions regarding the

fiduciary duties of governing body members, the composition of the governing body, and conflict of interest policies (§ 425.106(b)(5)).

We noted in the proposed rule that some applicants questioned when an ACO needs to be formed as a separate legal entity, particularly the meaning in § 425.104(b) of “otherwise independent” ACO participants. Specifically, applicants questioned whether multiple prospective ACO participants are “otherwise independent” when they have a prior relationship through, for example, an integrated health system. In addition, we received some questions regarding compliance with the governing body requirements set forth in § 425.106(b)(4) and (5). For example, we received questions from some IPAs, each of which wanted to apply to the Shared Savings Program as an ACO using its existing legal structure and governing body. In some cases, the IPA represented many group practices, but not every group practice represented by an IPA had agreed to be an ACO participant. In the proposed rule, we stated that that such an IPA would need to organize its ACO as a separate legal entity with its own governing body to ensure that the governing body members would have a fiduciary duty to the ACO alone, as required by § 425.106(b)(3), and not to an entity comprised in part by entities that are not ACO participants.

(2) Proposed Revisions

We proposed to clarify our regulation text regarding when an ACO must be formed as a separate legal entity. Specifically, we proposed to remove the reference to “otherwise independent ACO participants” in § 425.104(b). The revised regulation would provide that an ACO formed by “two or more ACO participants, each of which is identified by a unique TIN,” must be a legal entity separate from any of its ACO participants. For example, if an ACO is composed of three ACO participants, each of whom belongs to the same health system or IPA, the ACO must be a legal entity separate and distinct from any one of the three ACO participants.

In addition, we proposed to clarify § 425.106(a), which sets forth the general requirement that an ACO have an identifiable governing body with the ultimate authority to execute the functions of an ACO. Specifically, we proposed that the governing body must satisfy three criteria. First, the governing body of the ACO must be the same as the governing body of the legal entity that is the ACO. Second, in the case of an ACO that comprises multiple ACO

participants, the governing body must be separate and unique to the ACO and must not be the same as the governing body of any ACO participant. Third, the governing body must satisfy all other requirements set forth in § 425.106, including the fiduciary duty requirement. We noted that the second criterion incorporates the requirement that currently appears at § 425.106(b)(4), which provides that the governing body of the ACO must be separate and unique to the ACO in cases where there are multiple ACO participants.

Accordingly, we proposed to remove § 425.106(b)(4). We further proposed to remove § 425.106(b)(5), which provides that if an ACO is an existing legal entity, its governing body may be the same as the governing body of that existing entity, provided that it satisfies the other requirements of § 425.106. In light of our proposed revision to § 425.106(a), we believe this provision is unnecessary and should be removed to avoid confusion. In proposing that the governing body be the same as the governing body of the ACO legal entity and that the governing body has ultimate authority to execute the function of the ACO we intended to preclude:

- Delegation of all ACO decision-making authority to a committee of the governing body. We recognize that the governing body of the legal entity that is the ACO may wish to organize committees that address certain matters pertaining to the ACO, but we do not believe that such committees can constitute the governing body of the ACO.

- Retention of ACO decision-making authority by a parent company. We recognize that a parent organization may wish to retain certain authorities to protect the parent company and ensure the subsidiary’s success. However, the ACO’s governing body must retain the ultimate authority to execute the functions of an ACO. As stated in the regulations, we believe such functions include such things as developing and implementing the required processes under § 425.112 and holding leadership and management accountable for the ACO’s activities. We also believe this authority extends to such activities including the appointment and removal of members of the governing body, leadership, and management, and determining how shared savings are used and distributed among ACO participants and ACO providers/suppliers.

The purpose of the new provision precluding the governing body of the ACO from being the same as the governing body of an ACO participant is

to ensure that the interests of individuals and entities other than the ACO do not improperly influence decisions made on behalf of the ACO. In order to comply with the requirement that the governing body be separate and unique to the ACO, it must not be responsible for representing the interests of any entity participating in the ACO or any entity that is not participating in the ACO. Thus, we proposed the requirement that an ACO's governing body must not be the same as the governing body of any of the ACO participants.

Comment: Several commenters noted that an ACO formed by "two or more ACO participants, each of which is identified by a unique TIN," must be a legal entity separate from any of its ACO participants. A commenter indicated that requirement for a separate legal entity with a governing body unaffiliated with the ACO participants creates unnecessary administrative burdens and leads to inconsistencies in the application of policies and procedures that are necessary to manage population health, coordinate care, and control costs.

Some commenters were supportive of the three criteria. A commenter stated that the governance requirements are overly intrusive and that CMS should moderate the proposed requirements to allow providers to use their current structures, rather than requiring them to develop a separate entity and governing body. Some commenters disagreed with the requirement that the ACO governing body retain ultimate authority to care out ACO activities in cases where the ACO has a parent company because they believe this requirement would erode the parent company's ability to protect its own interests.

Response: Section 1899(b)(2)(C) of the Act requires the ACO to have a formal legal structure that allows the organization to receive and distribute shared savings payments to ACO participants and ACO providers/suppliers. As stated in the November 2011 final rule, we continue to believe that the requirement for an ACO to have a legal entity and governing body that is separate from any of the ACO participants that have joined to form the ACO is essential to promote program integrity broadly, including protecting against fraud and abuse, and to ensure the ACO is accountable for its responsibilities under the Shared Savings Program. We do not believe that the formation of a separate legal entity is overly burdensome. The proposal would codify current policy which all participating ACOs have satisfied. Rather than trying to integrate the

policies and procedures from multiple participants, the ACO and its governing body (made up and directed by the ACO participants that joined to form the ACO) is in the best position to determine what uniform policies and procedures to apply across the ACO. We note that the legal entities of many ACOs and their governing bodies oversee operations for participation in private payer ACOs in addition to participation in the Shared Savings Program. Shared Savings Program ACOs may do this, so long as their governing bodies meet the fiduciary duty requirements as discussed later. Our proposal was not intended to repudiate our existing policy (and the corollary of proposed § 425.104(b)) that an ACO formed by a single ACO participant need not form a separate legal entity to operate the ACO and is permitted to use its existing governing body, as long as it can meet the other eligibility and governance requirements of the program. We will add a new paragraph (c) at § 425.104 to clarify this point.

As stated in the November 2011 final rule, we believe it is important for the ACO to establish an identifiable governing body that retains ultimate authority because the ACO is ultimately responsible for its success or failure. The criteria are also important to help insulate against conflicts of interest that could potentially put the interest of an ACO participant or parent company before the interests of the ACO. We note that many ACOs have been developed with the assistance of parent organizations that desire to protect their own interests. However, the parent company's own interests must not interfere with the ACO's ultimate authority and obligation to comply with the requirements of the Shared Savings Program. Nor must those interests interfere with the fiduciary duty of the ACO's governing body as discussed later in this section. Therefore, we will finalize the proposed criteria. However, in response to the commenters, we will clarify the regulation text at § 425.106(a)(2)(ii) to provide that, the governing body of an ACO formed by a single ACO participant would be the governing body of the ACO participant.

FINAL ACTION: We are finalizing our proposal to remove the reference to "otherwise independent ACO participants" in § 425.104(b). The revised regulation would provide that an ACO formed by "two or more ACO participants, each of which is identified by a unique TIN," must be a legal entity separate from any of its ACO participants. In response to the commenters, we are adding new § 425.104(c) to clarify that an ACO

formed by a single ACO participant may use its existing legal entity and governing body, provided it satisfies the other requirements in §§ 425.104 and 425.106. Additionally, we are finalizing at § 425.106(a)(2) our proposal that the governing body must satisfy three criteria: First, the governing body of the ACO must be the same as the governing body of the legal entity that is the ACO. Second, in the case of an ACO that comprises multiple ACO participants the governing body must be separate and unique to the ACO, except as provided in § 425.104(c). Third, the governing body must satisfy all other requirements set forth in § 425.106, including the fiduciary duty requirement. We are finalizing our proposal to remove §§ 425.106(b)(4) and (5).

b. Fiduciary Duties of Governing Body Members

(1) Overview

Our current regulations at § 425.106(b)(3) require that the governing body members have a fiduciary duty to the ACO and must act consistent with that duty. We have clarified in guidance that the governing body members cannot meet the fiduciary duty requirement if the governing body is also responsible for governing the activities of individuals or entities that are not part of the ACO (See "Additional Guidance for Medicare Shared Savings Program Accountable Care Organization (ACO) Applicants" located online at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Memo_Additional_Guidance_on_ACO_Participants.pdf). For example, in the case of an IPA that applies as an ACO to the Shared Savings Program, we believe it would be difficult for the members of the IPA's governing body to make decisions in the best interests of the ACO if only some of the group practices that compose the IPA are ACO participants; decisions affecting the ACO may be improperly influenced by the interests of group practices that are part of the IPA but are not ACO participants. For this reason, our regulations require the IPA to establish the ACO as a separate legal entity. This new legal entity must have a governing body whose members have a fiduciary responsibility to the ACO alone and not to any other individual or entity.

(2) Proposed Revisions

We proposed to clarify in § 425.106(b)(3) that the fiduciary duty owed to an ACO by its governing body

members includes the duty of loyalty. The purpose of the proposal was to emphasize that the ACO's governing body decisions must be free from the influence of interests that may conflict with the ACO's interests. This proposal does not represent a change in policy and is simply intended to underscore that members of an ACO governing body must not have divided loyalties; they must act only in the best interests of the ACO and not another individual or entity, including the individual interests of ACO participants, ACO professionals, ACO providers/suppliers, or other individuals or entities.

Comment: Several commenters expressed specific support for the concept that the fiduciary duty owed to an ACO by its governing body members includes the duty of loyalty. A commenter recommended clarification that the requirement would not preclude members of the governing body from participating either on governing bodies or in senior management roles of other organizations.

Response: We appreciate the comments received on our proposal to include the duty of loyalty as one of the fiduciary duties owed to the ACO by the members of its governing body. We believe that it is possible for members of the ACO's governing body to hold similar leadership positions in other organizations. However, when acting on behalf of the ACO, each governing body member must act in the best interests of the ACO. We note that the ACO governing body is required under § 425.106(d) to have a conflict of interest policy that requires each member of the governing body to disclose relevant financial interests, provide a procedure for determining whether a conflict of interest exists and set forth a process to address any conflicts that arise. Additionally, the conflict of interest policy must address remedial action for members of the governing body that fail to comply with the policy. We believe this safeguard can ensure that governing body members act with a duty of loyalty.

FINAL ACTION: We will finalize our proposal to clarify at § 425.106(b)(3) that the fiduciary duty owed to an ACO by its governing body members includes the duty of loyalty.

c. Composition of the Governing Body

(1) Overview

Section 1899(b)(1) of the Act requires an ACO to have a "mechanism for shared governance" among ACO participants. Section 425.106(c)(1) of the regulations requires an ACO to provide

for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives. As we explained in the November 2011 final rule (76 FR 67819), we believe that an ACO should be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries. However, we acknowledged that small groups of providers often lack both the capital and infrastructure necessary to form an ACO and to administer the programmatic requirements of the Shared Savings Program and could benefit from partnerships with non-Medicare enrolled entities. For this reason, we proposed (76 FR 19541) that to be eligible for participation in the Shared Savings Program, the ACO participants must have at least 75 percent control of the ACO's governing body. In the November 2011 final rule, we explained that this requirement would ensure that ACOs remain provider-driven, but also leave room for non-providers to participate in the program.

In addition, to provide for patient involvement in the ACO governing process, we specified at § 425.106(c)(2) that an ACO's governing body must include a Medicare beneficiary served by the ACO who does not have a conflict of interest with the ACO. We acknowledged in the November 2011 final rule that beneficiary representation on an ACO's governing body might not always be feasible. For example, commenters raised concerns that requiring a beneficiary on the governing body could conflict with state corporate practice of medicine laws or other local laws regarding governing body requirements for public health or higher education institutions (76 FR 67821). As a result, we believe it was appropriate to provide some flexibility for us to permit an ACO to adopt an alternative structure for its governing body, while still ensuring that ACO participants and Medicare FFS beneficiaries are involved in ACO governance.

Accordingly, our existing regulations offer some flexibility to permit an ACO to participate in the Shared Savings Program even if its governing body fails to include a beneficiary or satisfy the requirement that 75 percent of the governing body be controlled by ACO participants. Specifically, § 425.106(c)(5) provides that if an ACO's governing body does not meet either the 75 percent threshold or the requirement regarding beneficiary representation, it must describe in its application how the proposed structure of its governing body would involve ACO participants in innovative ways in ACO governance or

provide a meaningful opportunity for beneficiaries to participate in the governance of the ACO. For example, under this provision, we anticipated that exceptions might be needed for ACOs that operate in states with Corporate Practice of Medicine restrictions to structure beneficiary representation accordingly. We contemplated that this provision could also be used by an existing entity to explain why it should not be required to reconfigure its board if it had other means of addressing the requirement to include a consumer perspective in governance (see 76 FR 67821).

(2) Proposed Revisions

We proposed to revise § 425.106(c)(1) to state the statutory standard in section 1899(b)(1) of the Act requiring an ACO to have a "mechanism for shared governance" among ACO participants. Although in the November 2011 final rule we did not announce a requirement that each ACO participant be a member of the ACO's governing body (76 FR 67818), the governing body must represent a mechanism for shared governance among ACO participants. Therefore, the governing body of an ACO that is composed of more than one ACO participant should not, for example, include representatives from only one ACO participant. For ACOs that have extensive ACO participant lists, we would expect to see representatives from many different ACO participants on the governing body. Our proposal to state the statutory standard for shared governance in our regulations at § 425.106(c)(1) does not constitute a substantive change to the program.

We also proposed to revise § 425.106(c)(2) to explicitly prohibit an ACO provider/supplier from being the beneficiary representative on the governing body. Some ACO applicants have proposed that one of their ACO providers/suppliers would serve as the beneficiary representative on the governing body. We believe it would be very difficult for an ACO provider/supplier who is a Medicare beneficiary to represent only the interests of beneficiaries, rather than his or her own interests as an ACO provider/supplier, the interests of other ACO providers/suppliers, or the interests of the ACO participant through which he or she bills Medicare.

We proposed to revise § 425.106(c)(5) to remove the flexibility for ACOs to deviate from the requirement that at least 75 percent control of an ACO's governing body must be held by ACO participants. Based on our experience to date with implementing the program,

we have learned that ACO applicants do not have difficulty meeting the requirement under § 425.106(c)(3) that ACO participants maintain 75 percent control of the governing body. We have not denied participation to any ACO applicants solely on the basis of failure to comply with this requirement, and it has not been necessary to grant any exceptions to this rule under § 425.106(c)(5). To the contrary, we have found the 75 percent control requirement to be necessary and protective of the ACO participant's interests. Accordingly, we believe there is no reason to continue to offer an exception to the rule.

We believe that it is important to maintain the flexibility for ACOs to request innovative ways to provide meaningful representation of Medicare beneficiaries on ACO governing bodies. Based on our experience, some ACOs have been unable to include a beneficiary on their governing body, and these entities have used the process under § 425.106(c)(5) to establish that they satisfy the requirement for meaningful beneficiary representation through the use of patient advisory bodies that report to the governing body of the ACO.

Comment: We received a few comments in support of our proposal to revise § 425.106(c)(5) to remove the flexibility for ACOs to deviate from the requirement that at least 75 percent control of an ACO's governing body must be held by ACO participants. However, several commenters recommended retention of this flexibility. The commenters opposed to its removal stated that such flexibility, although not currently used or required, could be necessary for future applicants. A commenter noted that true decision-making by an ACO governing body that broadly represents ACO participants could be achieved in a number of ways.

Response: As stated in the November 2011 final rule, we believe the 75-percent control requirement is necessary to ensure that ACOs are provider driven. Therefore, we finalized this requirement but permitted an exception in case there were state laws or other impediments that would limit an ACO's ability to comply with it. However, our experience over several application cycles has demonstrated that stakeholder concern over conflicts with laws governing the composition of tax-exempt or state-licensed entities does not appear to have been a factor in the ability of ACOs to comply with this requirement. Moreover, our experience to date leads us to conclude that this requirement ensures that the ACO participants who have joined to form

the ACO have direct and primary influence and input on the required functions of the ACO, rather than external third parties. However, given that the program is still in the early stages of implementation and our relatively limited experience with ACOs in two-sided risk tracks, we will retain the flexibility for an ACO to request an exception to the 75-percent control requirement. We anticipate permitting such exceptions only in very limited circumstances (for example, when the ACO demonstrates that it is unable to comply because of a conflict with other laws).

Comment: Several commenters agreed with our proposed revision to § 425.106(c)(2) to explicitly prohibit an ACO provider/supplier from being the beneficiary representative on the governing body. A commenter stated that CMS to strengthen the requirements for meaningful involvement of consumer/beneficiary representatives increase the number of beneficiaries on the governing body and to exercise greater oversight to ensure the success of beneficiary engagement efforts. Several commenters offered additional suggestions for members of the governing body, including requiring the ACO to involve patient/family representatives on ACO quality and safety improvement committees or considering a requirement that consumer advocates, employers, labor organizations and other community organizations or "other entities" (such as post-acute care providers) be represented on the governing body. A commenter opposed the flexibility afforded under § 425.106(c)(5) for the ACO to differ from the requirement to have a beneficiary on the governing body stating that this section creates a loophole for ACOs to avoid the requirement. In addition, this commenter further suggested that all ACO applications should be required to include details regarding how the ACO intends to involve Medicare beneficiaries in innovative and meaningful ways that enhance patient engagement and coordination of care.

Response: We appreciate the comments received on this proposal. As stated in the November 2011 final rule (FR 76 67821), we believe that a focus on the beneficiary in all facets of ACO governance are critical for ACOs to achieve the three-part aim and believe that beneficiary representation is important. Therefore, we continue to encourage ACOs to consider seriously how to provide opportunities for beneficiaries and others to be involved in ACO governance through both governing body representation and other

appropriate mechanisms. However, as articulated in the November 2011 final rule, we believe our current regulations balance our overall objectives for the program while permitting ACOs flexibility to structure their governing bodies appropriately; therefore, we are unable to incorporate suggestions to increase the beneficiary representation requirement and suggestions for governing body representation of other consumer or provider entities.

As we noted in the November 2011 final rule, we recognize there may be state corporate practice of medicine laws or other reasons why it may not be feasible for a beneficiary to be represented on the ACO's governing body and therefore finalized a policy that permits an ACO to apply for an exception to the rule that an ACO must have a beneficiary on the governing body. Very few of these exceptions have been granted to date. In these few cases, ACOs have developed patient advisory committees that report directly to the ACO's governing body. ACOs have reported that such a committee can have a very strong influence on governing body decisions and involve more beneficiary voices than would have otherwise been able by having a single beneficiary on the governing body. Therefore, we believe it is important to continue to permit flexibility for ACOs to deviate from this requirement.

FINAL ACTION: Because we received no comments on our proposed revision to § 425.106(c)(1), we are finalizing our proposal to modify that provision to state the statutory standard in section 1899(b)(1) of the Act, which requires an ACO to have a "mechanism for shared governance" among ACO participants. We are also finalizing our proposed revision to § 425.106(c)(2) to explicitly prohibit an ACO provider/supplier from being the beneficiary representative on the governing body.

We are not finalizing our proposal to remove § 425.106(c)(5), which offers flexibility for ACOs to deviate from the requirement that ACO participants must hold at least 75 percent control of an ACO's governing body. However, we note that we anticipate permitting such exceptions only in very limited circumstances. We may revisit this issue in future rulemaking.

7. Leadership and Management Structure

a. Overview

Section 1899(b)(2)(F) of the Act requires an eligible ACO to "have in place a leadership and management structure that includes clinical and administrative systems." Under this

authority, we incorporated certain leadership and management requirements into the Shared Savings Program, as part of the eligibility requirements for program participation. In the November 2011 final rule (76 FR 67822), we stated that an ACO's leadership and management structure should align with and support the goals of the Shared Savings Program and the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.

In the November 2011 final rule (76 FR 67825), we established the requirement that the ACO's operations be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes (see § 425.108(b)). In addition, under § 425.108(c), clinical management and oversight must be managed by a senior-level medical director who is one of the ACO providers/suppliers, who is physically present on a regular basis in an established ACO location (clinic, office or other location participating in the ACO), and who is a board-certified physician licensed in a state in which the ACO operates. In § 425.204(c)(1)(iii), we require ACO applicants to submit materials documenting the ACO's organization and management structure, including senior administrative and clinical leaders specified in § 425.108.

In the November 2011 final rule (76 FR 67825), we provided flexibility for ACOs to request an exception to the leadership and management requirements set forth under § 425.108(b) and (c). We believe that affording this flexibility was appropriate in order to encourage innovation in ACO leadership and management structures. In accordance with § 425.108(e), we may give consideration to an innovative ACO leadership and management structure that does not comply with the requirements of § 425.108(b) and (c).

We stated in the proposed rule that we continued to believe that having these key leaders (operational manager and clinical medical director) is necessary for a well-functioning and clinically integrated ACO. We noted that after four application cycles, it appeared that ACO applicants do not have difficulty in meeting the operational manager and clinical medical director requirements. Only one ACO had requested an exception to the medical director requirements. In that

case, the ACO sought the exception in order to allow a physician, who had retired after a long tenure with the organization to serve as the medical director of the ACO. We approved this request because, although the retired physician was not an ACO provider/supplier because the retired physician was no longer billing for physician services furnished during the agreement period, he was closely associated with the clinical operations of the ACO, familiar with the ACO's organizational culture, and dedicated to this one ACO.

In addition, we noted that we had received a number of questions from ACO applicants regarding the other types of roles for which CMS requires documentation under § 425.204(c)(1)(iii) to evaluate whether an applicant has a “. . . leadership and management structure that includes clinical and administrative systems” that support the purposes of the Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures, as articulated at § 425.108(a). We stated that in response to such inquiries we considered an ACO's “. . . leadership and management structure that includes clinical and administrative systems” to be composed of the operational manager and clinical medical director (referenced under § 425.108(b) and (c)) as well as the qualified healthcare professional that is required under § 425.112(a) to be responsible for the ACO's quality assurance and improvement program.

b. Proposed Revisions

We proposed to amend § 425.108 to provide some additional flexibility regarding the qualifications of the ACO medical director and to eliminate the provision permitting some ACOs to enter the program without satisfying the requirements at § 425.108(b) and (c) for operations and clinical management. In addition, we proposed to amend § 425.204(c)(iii) to clarify that applicants must submit materials regarding the qualified health care professional responsible for the ACO's quality assurance and improvement program.

We stated our belief that it was appropriate to amend the medical director requirement at § 425.108(c) to allow some additional flexibility. Specifically, we proposed to remove the requirement that the medical director be an ACO provider/supplier. This change would permit an ACO to have a medical director who was, for example, previously closely associated with an ACO participant but who is not an ACO provider/supplier because he or she

does not bill through the TIN of an ACO participant and is not on the list of ACO providers/suppliers. Alternatively, we considered retaining the requirement that an ACO's medical director be an ACO provider/supplier, but permitting ACOs to request CMS approval to designate as its medical director a physician who is not an ACO provider/supplier but who is closely associated with the ACO and satisfies all of the other medical director requirements. We sought comment on whether an ACO medical director who is not an ACO provider/supplier must have been closely associated with the ACO or an ACO participant in the recent past. In addition, we proposed to clarify that the medical director must be physically present on a regular basis “at any clinic, office, or other location of the ACO, an ACO participant or an ACO provider/supplier.” Currently, the provision incorrectly refers only to locations “participating in the ACO.”

However, we stated we continued to believe that the medical director of the ACO should be directly associated with the ACO's clinical operations and familiar with the ACO's organizational culture. We noted that this is one purpose of the provision requiring medical directors to be physically present on a regular basis at any clinic, office, or other ACO location. A close working relationship with the ACO and its clinical operations is necessary in order for the medical director to lead the ACO's efforts to achieve quality improvement and cost efficiencies.

Additionally, we proposed to eliminate § 425.108(e), which permits us to approve applications from innovative ACOs that do not satisfy the leadership and management requirements related to operations management and clinical management and oversight set forth at § 425.108(b) and (c). Based on our experience with the program and the proposed change to the medical director requirement, we stated our belief that it was unnecessary to continue to allow ACOs the flexibility to request an exception to the leadership and management requirements related to operations management and clinical management and oversight (§ 425.108(b) and (c)). We noted that these requirements are broad and flexible and have not posed a barrier to participation in the Shared Savings Program; in fact, in only one instance has an ACO requested an exception to the operations management criterion (§ 425.108(b)). We were unaware of any alternative operations management structure that might be considered acceptable, and we proposed to modify § 425.108(c) to accommodate the one exception we

have granted to date. Accordingly, we proposed to revise the regulations by striking § 425.108(e) to eliminate the flexibility for ACOs to request an exception to the leadership and management requirements at § 425.108(b) and (c).

Finally, to clarify questions that have been raised by ACO applicants and to reduce the need for application corrections, we proposed to modify § 425.204(c)(1)(iii) to require a Shared Savings Program applicant to submit documentation regarding the qualified healthcare professional responsible for the ACO's quality assurance and improvement program (as required by § 425.112(a)).

We sought comment on these changes to the requirements for ACO leadership and management.

Comment: Many commenters supported our proposal revision to § 425.108(c) to permit more flexibility for the medical director of an ACO. These commenters stated that a medical director should not be limited to being a current ACO provider/supplier because the ACO should have flexibility to conduct a nationwide search for the best candidate. Moreover, these commenters noted that many potentially qualified physicians have navigated away from patient care toward more administrative activities, thereby developing expertise in areas desirable in a medical director and necessary for ACO success. However, several commenters opposed the proposal to introduce flexibility. These commenters believe that a successful ACO medical director is one who is directly associated with the clinical operations of the ACO and familiar with its organizational culture, or should otherwise be able to provide direct patient care.

A few commenters urged CMS to allow even more flexibility than what was proposed. These commenters suggested alternative criteria for qualifications of the medical director. For example, some commenters suggested that we permit the medical director position to be filled by individuals other than physicians, such as an advance practice nurse or other qualified health professional.

Response: As stated in the November 2011 final rule, we believe physician leadership of clinical management and oversight is important to the ACO's ability to achieve the three-part aim. We agree with commenters who indicate that flexibility may be necessary for the ACO to select the best qualified physician for this role. We also agree with commenters that the best physician for the role of medical director may be

one who has an intimate knowledge of the ACO's organizational culture or who is actively implementing (through direct patient care activities) the clinical processes established by the ACO. We believe it is important to ensure that the medical director is familiar with the day-to-day operations of the ACO. We believe our proposals balanced these perspectives by eliminating the requirement that the medical director be an ACO provider/supplier while also clarifying the requirement that the medical director be physically present on a regular basis "at any clinic, office, or other location of the ACO, ACO participant or ACO provider/supplier." We will therefore finalize the modifications as proposed and permit ACOs to choose a medical director who best suits the ACO's goals and needs.

We appreciate additional suggestions for modifications in the criteria for the ACO's medical director and will keep them in mind in future rulemaking. Specifically, we appreciate the comments suggesting that the medical director could be any qualified health professional. We will not modify our requirements for the medical director in this manner because ACOs report that physician leadership is an important key to the success of the ACO. Additionally, the ACO is required to have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program, in addition to the medical director and may choose to appoint non-physician clinical leaders to this role. We discuss modifications to this requirement later in this section.

Comment: A number of commenters provided feedback on the proposed elimination of § 425.108(e), which permits CMS to approve applications from innovative ACOs that do not satisfy the leadership and management requirements related to operations management and clinical management and oversight set forth at § 425.108(b) and (c). A commenter supported the removal of this provision, although other commenters suggested this flexibility could be necessary for future applicants for the program.

Response: In the November 2011 final rule, we finalized a policy in which CMS retained the right to give consideration to innovative ACOs that did not include: (1) operations managed by an executive, officer, manager, general partner, or similar party; and (2) clinical management and oversight by a senior-level medical director. Given our experience with the program, the additional flexibility provided in this final rule regarding the medical director qualifications, and the fact that these

requirements are already so broad and flexible, we do not believe that any additional flexibility is necessary or even possible. Therefore, we are finalizing our proposal to eliminate § 425.108(e). As noted previously, we clarified that we consider the qualified health professional referenced in § 425.112(a) to be part of the ACO's leadership and management team and as such, we proposed to modify § 425.204(c)(1)(iii) to require a Shared Savings Program applicant to submit documentation regarding this person, if the role is not filled by the medical director.

Comment: Some commenters agreed with CMS' proposal and requested that CMS consider providing more guidance that would describe suitable training, experience, and knowledge for how to run an effective quality assurance and improvement program. Other commenters disagreed with our proposal, stating that CMS should not require documentation of the qualifications of such a professional.

Response: We believe it is important for the ACO to include a person within its clinical leadership team that is directly responsible for the ACO's quality assurance and improvement program. This person, as discussed in the November 2011 final rule, may be a physician or any other qualified health professional. We clarify that this role may be filled by the ACO's medical director. Currently, in the ACO's application to the Shared Savings Program, we request certain information about the ACO's organization and management structure. Because the quality assurance and improvement program is integral to the ACO's ability to meet participation requirements, we also believe the healthcare professional responsible for it must be considered a part of the ACO's clinical leadership. Therefore, we are finalizing our proposal that the ACO submit information about this person as part of its application to the program.

FINAL ACTION: We are finalizing, as proposed, our policies related to the ACO's leadership and management. Specifically, we are amending § 425.108 to provide some additional flexibility regarding the qualifications of the ACO medical director and to eliminate the provision permitting ACOs to request consideration to enter the program without satisfying the requirements at § 425.108(b) and (c) for operations and clinical management. In addition, we are amending § 425.204(c)(iii) to require that applicants must submit materials at the time of application regarding the ACO's leadership and management team, including the qualified health care

professional responsible for the ACO's quality assurance and improvement program.

8. Required Process To Coordinate Care

a. Overview

Section 1899(b)(2)(G) of the Act requires an ACO to "define processes to . . . coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies." In the November 2011 final rule (76 FR 67829 through 67830), we established requirements under § 425.112(b)(4) that ACOs define their care coordination processes across and among primary care physicians, specialists, and acute and post-acute providers. As part of this requirement, an ACO must define its methods and processes to coordinate care throughout an episode of care and during its transitions. In its application to participate in the Shared Savings Program, the ACO must submit a description of its individualized care program, along with a sample care plan, and explain how this program is used to promote improved outcomes for, at a minimum, its high-risk and multiple chronic condition patients. In addition, an ACO's application must describe target populations that would benefit from individualized care plans.

In developing these policies for the November 2011 final rule (76 FR 67819), we received comments acknowledging that requiring ACOs to define processes to promote coordination of care is vital to the success of the Shared Savings Program. Commenters stressed the importance of health information exchanges in coordination of care activities and recommended that CMS allow ACOs the flexibility to use any standards-based electronic care coordination tools that meet their needs. Other commenters suggested that the proposed rule anticipated a level of functional health information exchange and technology adoption that may be too aggressive.

As stated in § 425.204(c)(1)(ii), applicants to the Shared Savings Program must provide a description, or documents sufficient to describe, how the ACO will implement the required processes and patient-centeredness criteria under § 425.112, including descriptions of the remedial processes and penalties (including the potential for expulsion) that will apply if an ACO participant or an ACO provider/supplier fails to comply with and implement these processes. Under § 425.112(b), an ACO must establish processes to accomplish the following:

- Promote evidence-based medicine.

- Promote patient engagement.
- Develop an infrastructure to internally report on quality and cost metrics required for monitoring and feedback.
- Coordinate care across and among primary care physicians, specialists and acute and post-acute providers and suppliers.

In addition to the processes described previously, we believe it is important for applicants to explain how they will develop the health information technology tools and infrastructure to accomplish care coordination across and among physicians and providers. Adoption of health information technology is important for supporting care coordination by ACO participants and other providers outside the ACO in the following ways:

- Secure, private sharing of patient information.
- Reporting on quality data and aggregating data across providers and sites to track quality measures.
- Deploying clinical decision support tools that provide access to alerts and evidence based-guidelines.

As ACOs establish more mature processes for risk management, information technology infrastructure allows ACOs and providers to conduct robust financial management of beneficiary populations, deliver cost and quality feedback reporting to individual providers, and streamline the administration of risk based contracts across multiple payers. We believe that requiring ACOs to address health information technology infrastructure in their application to the Shared Savings program would support more careful planning and increased focus on this issue.

b. Accelerating Health Information Exchange

We believe all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (HHS August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange") HHS is committed to accelerating health information exchange (HIE) through the use of EHRs and other types of health information technology (HIT) across the broader care continuum through a number of initiatives including—

- Establishing a coordinated governance framework and process for nationwide health IT interoperability;

- Improving technical standards and implementation guidance for sharing and using a common clinical data set;
- Enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and
- Clarifying privacy and security requirements that enable interoperability. These initiatives are designed to encourage HIE among health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those ineligible for such programs to improve care delivery and coordination across the entire care continuum.

For example, the Transition of Care Measure #2 in Stage 2 of the Medicare and Medicaid EHR Incentive Programs requires HIE to share summary records for at least 10 percent of care transitions. Most recently, the Office of the National Coordinator for Health Information Technology (ONC) released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap" (available at <http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf>) which further describes a shared agenda for achieving interoperability across the current health IT landscape. In the near term, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017.

We believe that HIE and the use of certified EHRs can effectively and efficiently help ACOs and participating providers improve internal care delivery practices, support management of patient care across the continuum, and support the reporting of electronically specified clinical quality measures (eCQMs).

c. Proposed Revisions

In the proposed rule, we continue to believe that ACOs should coordinate care between all types of providers and across all services, and that the secure, electronic exchange of health information across all providers and suppliers is of the utmost importance for both effective care coordination activities and the success of the Shared Savings Program. We clarify that such care coordination could include coordination with community-based organizations that provide services that address social determinants of health. We understand that ACOs will differ in their ability to adopt the appropriate

health information exchange technologies, but we continued to underscore the importance of robust health information exchange tools in effective care coordination.

In the proposed rule, ACOs have reported how important access to real time data is for providers to improve care coordination across all sites of care, including outpatient, acute, and post-acute sites of care. We believe that providers across the continuum of care are essential partners to primary care physicians in the management of patient care. ACOs participating in the program indicate that they are actively developing the necessary infrastructure and have been encouraging the use of technologies that enable real time data sharing among and between sites of care. We believe having a process and plan in place to coordinate a beneficiary's care by electronically sharing health information improves care, and that this helps all clinicians involved in the care of a patient to securely access the necessary health information in a timely manner. It also can also be used to engage beneficiaries in their own care. We further believe that Shared Savings Program applicants should provide, as part of the application, their plans for improving care coordination by developing, encouraging, and using enabling technologies and electronic health records to make health information electronically available to all practitioners involved in a beneficiary's care.

Therefore, we proposed to add a new requirement to the eligibility requirements under § 425.112(b)(4)(ii)(C) which would require an ACO to describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries. Such enabling technologies and services may include electronic health records and other health IT tools (such as population health management and data aggregation and analytic tools), telehealth services (including remote patient monitoring), health information exchange services, or other electronic tools to engage patients in their care. We also proposed to add a new provision at § 425.112(b)(4)(ii)(D) to require the applicant to describe how the ACO intends to partner with long-term and post-acute care providers to improve care coordination for the ACO's assigned beneficiaries. Finally, we proposed to add a provision under § 425.112(b)(4)(ii)(E) to require that an ACO define and submit major milestones or performance targets it will

use in each performance year to assess the progress of its ACO participants in implementing the elements required under § 425.112(b)(4). For instance, providers would be required to submit milestones and targets such as: Projected dates for implementation of an electronic quality reporting infrastructure for participants; the number of providers expected to be connected to health information exchange services by year; or the projected dates for implementing elements of their care coordination approach, such as alert notifications on emergency department and hospital visits or e-care plan tools for virtual care teams. We believe this information would allow us to better understand and support ACOs' plans to put into place the systems and processes needed to deliver high quality care to beneficiaries.

We also noted that ACOs have flexibility to use telehealth services, as they deem appropriate for their efforts to improve care and avoid unnecessary costs. Some ACOs have already reported that they are actively using telehealth services to improve care for their beneficiaries. We welcomed information from ACOs and other stakeholders about the use of such technologies. We sought comment on the specific services and functions of this technology that might be appropriately adopted by ACOs. For example, do the use of telehealth services and other technologies necessitate any additional protections for beneficiaries? Are these technologies necessary for care coordination or could other methods be used for care coordination? If a particular technology is necessary, under what circumstances?

Comment: Several commenters supported our proposed new provision at § 425.112(b)(4)(ii)(D) to require the applicant to describe how the ACO intends to partner with long-term and post-acute care providers to improve care coordination for the ACO's assigned beneficiaries. A commenter noted that recent studies have established that use of post-acute care contributes to the most variation in expenditures for Medicare beneficiaries. Another commenter suggested that CMS evaluate whether the requirement for ACOs to define a process to promote care coordination is sufficiently patient-centered.

Commenters also stated that post-acute care should include both community-based and facility-based long-term services and other supporting practitioners. Several commenters noted their belief that primary care physicians are the key to improving care coordination. A commenter noted that

nurse practitioners play a contributing role in the implementation of care coordination activities across ACO professionals within the ACO. A few commenters recommended that CMS create an additional requirement for ACOs to describe how it will provide beneficiaries with palliative care services.

A few commenters disagreed with the addition of any requirements, stating that they believe this requirement would add administrative burden to ACOs and distract from coordination of care. A commenter opposed care coordination requirements and the current requirement at § 425.112(a)(3)(i) for ACOs to outline remedial processes and penalties that would apply for provider non-compliance and suggested CMS eliminate them.

Response: We appreciate the broad support for the program rules requiring ACOs to develop a process to promote patient-centered care coordination, including the requirements for the ACO to define this process across sites of care. We believe that our current rules place a strong emphasis on patient-centeredness and refer the reader to the November 2011 proposed and final rules for a more fulsome discussion of this important issue. Our current rules require ACOs to define, establish, implement, evaluate, and periodically update its care processes, including its process to coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers. When engaging beneficiaries and in shared decision-making, the ACO must take into account the beneficiaries' unique needs, preferences, values, and priorities. Individualized care plans must take into account community resources available to the individual. Therefore, we believe that the ACO's care coordination efforts could include both community-based and facility-based long-term services and other supporting practitioners. Furthermore, we agree that primary care practitioners are central to the ACO's efforts to improve care coordination for the assigned beneficiary population and that many clinical and administrative personnel, including nurse practitioners and other non-physician practitioners, play an important contributing role in the implementation of care coordination activities for the ACO. Our rules at § 425.112(a)(3)(i) require each ACO to explain how it will require ACO participants and ACO providers/suppliers to comply with and implement each process (and all sub-elements of each process), including remedial processes and penalties (including the potential for expulsion)

applicable to ACO participant and ACO providers/suppliers for failure to comply with their implementation. We believe this is necessary because the processes are so integral to ACO participation and the mission of an ACO. We believe that compliance with these processes can indicate whether an ACO participant or ACO provider/supplier has made a meaningful commitment to the mission and success of the ACO.

We are not including other specific requirements at this time because we believe ACOs should have flexibility within the current rules to define care processes that are appropriate for their unique patient population. Therefore, we are finalizing the proposed policy without change.

Comment: Many commenters supported our proposed revision to add a new eligibility requirement under § 425.112(b)(4)(ii)(C) which would require an ACO to describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries. Commenters specifically encouraged CMS to require ACOs to use specific technologies such as EHRs, image sharing, mobile devices, electronic access for beneficiaries, HIT-enabled monitoring of performance on patient-reported outcomes, and remote patient monitoring. A commenter suggested requiring ACOs to give beneficiaries the ability to view, download, and transmit their health information in a manner consistent with Meaningful Use requirements. Supporters suggested modifications to the proposed provision such as recognizing that care coordination tools may be part of EHR functionality that care coordination tools may include innovative electronic care coordination applications, or that care coordination tools can be designed to assist both providers and beneficiaries. A commenter recommended that use of EHRs be a requirement for participation in the program, rather than a description in the application. Several commenters offered specific suggestions, such as requiring inpatient facilities to notify a patient's primary care provider immediately upon presentation to the emergency department, prior to admission, and on a daily basis when the patient has been admitted. A commenter recommended that CMS require ACOs to describe how it would use enabling technologies to engage patients. Another commenter encouraged CMS to consider the cultural needs, health literacy, and technological literacy of the community as components in the promotion of

enabling technologies. A commenter suggested CMS support transparency by evaluating and reporting on the best enabling technology outcomes to encourage ACO adoption of best practices. Another commenter made the statement that to enhance patient engagement and caregiver engagement of care, patient-facing information and communication platforms should be accessible to those with visual, hearing, cognitive, and communication impairments.

Several commenters raised concerns about the proposal stating that ACOs should have flexibility to work with their participating physicians and other health professionals on how best to deploy technology in a manner that drives efficiency and quality improvement. These commenters viewed the proposed policy as overly restrictive and a deterrent to the development of innovative enabling technologies. Some commenters agreed that health IT is a critical component of ACO success, but warned that a requirement such as this would just increase ACO burden and not ensure that health IT would actually be used effectively to transform care, in other words, enabling technologies should be understood as a means for care coordination and not an end unto itself. Commenters also raised a concern about the costs of such technologies and suggested CMS offer financial awards or bonuses to ACOs to defray the costs of acquiring technologies or hiring care coordinators to better implement care coordination processes.

Response: We appreciate the support of those that recognize the importance of encouraging ACO adoption of enabling technologies to improve care coordination. We agree that enabling technologies should be adopted thoughtfully with the goal of improving care, and not just adoption for its own sake. We are not finalizing additional specific requirements because we agree with commenters that ACOs should have flexibility to define their care coordination processes and use of enabling technologies. We believe this flexibility can encourage innovative methods of engaging both beneficiaries and providers in the coordination of a patient's care. ACOs should also have flexibility because of differences in the rate of adoption of enabling technologies, cultural needs and health literacy of the ACO's population. Additionally, we believe this flexibility is needed because it is too early in the adoption of enabling technologies to determine what processes or technologies produce the best outcomes for patients. We therefore disagree with

commenters that view the proposal as overly restrictive. As use of such technologies becomes more established, best practices may emerge in the future which CMS may consider. While we encourage ACO efforts to improve care coordination throughout episodes of care and during care transitions, we agree with commenters that additional requirements on providers would be burdensome. Therefore, at this time we will not require inpatient facilities to notify primary care providers of emergency room visits or admissions. However, we note that inpatient facilities have an interest in coordinating the care of beneficiaries to reduce avoidable admissions and encourage ACOs to develop relationships with local hospitals to improve these transitions.

We continue to believe ACOs should coordinate care between all types of providers and suppliers across all services, and secure, electronic exchange of health information across all providers in a community is of the utmost importance for both effective care coordination activities and the success of the Shared Savings Program. We believe having a process and plan in place to coordinate a beneficiary's care by electronically sharing health information improves care, and that this helps all clinicians involved in the care of a patient to securely access the necessary health information in a timely manner. We further believe that Shared Savings Program applicants should provide, as part of the application, their plans for improving care coordination by developing, encouraging, and using enabling technologies and electronic health records to make health information electronically available to all practitioners involved in a beneficiary's care, both within the ACO and with other practitioners and sites of care outside of the ACO involved in the care of a beneficiary. Therefore, we are finalizing our proposal to add a new requirement to the eligibility requirements under § 425.112(b)(4)(ii)(C) which will require an ACO to describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries. Specifically, such enabling technologies and services may include electronic health records and other health IT tools (such as population health management and data aggregation and analytic tools), telehealth services, remote patient monitoring, health information exchange services or other electronic tools to engage patients in their care.

In response to the comment suggesting that communications and information be accessible to people with impairments, we note that according to § 425.208(b), the ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities to comply with all applicable laws, including laws such as the Rehabilitation Act of 1973, to ensure access to enabling technologies for individuals with disabilities.

Comment: Several commenters supported our proposal to add a provision under § 425.112(b)(4)(ii)(E) to require that an ACO define and submit major milestones or performance targets that it will use in each performance year to assess the progress of its ACO participants in implementing the elements required under § 425.112(b)(4). However, a majority of commenters opposed this proposal. Commenters who supported the proposal indicated that they believe that milestones would be important to keep the ACO and ACO participants accountable to their care coordination plan. Others requested clarification on what the penalties would be if targets and milestones are not met as well as how often these targets and milestones must be reported by ACOs. Commenters who were opposed to the proposal stated that additional eligibility requirements would be an administrative burden and distract from the actual coordination of care. A commenter suggested the CMS amend this proposal to require that the ACO take into account the cultural needs, and health and technological literacy of the community when setting milestones. Another commenter wondered if this requirement would apply to ACOs renewing their participation agreements.

Response: We believe that setting milestones is important for an ACO to track its progress and the progress of its ACO participants in implementing care coordination activities and the use of enabling technologies. However, we agreed with commenters who believe the requirement to be overly burdensome. We note that although we are not finalizing this specific requirement at this time, ACOs are currently required under § 425.112(b)(4), as a condition of program eligibility and participation, to “define, establish, implement, evaluate, and periodically update” processes to promote care coordination among primary care physicians, specialist, and acute and post-acute providers and suppliers. We believe that the obligation to evaluate such processes necessarily

entails an evaluation of the ACO's progress in achieving care coordination. We will continue to monitor ACO progress on HIT infrastructure as part of program administration. In addition, we will assess general progress through ACO performance on measures related to HIT adoption and use, for instance, the current MSSP quality measure around participation in the EHR Incentives program, or a future measure which would reflect ACO providers' ability to electronically exchange data to support care transitions. We also encourage providers to monitor the degree of interoperability and exchange across providers in their ACO, which could include evaluating performance on the transition of care or health information exchange measures in the EHR Incentives Program.

FINAL ACTION: For the reasons previously discussed, we are finalizing our proposal to add a new requirement to the eligibility requirements under § 425.112(b)(4)(ii)(C) which will require an ACO to describe in its application how it will encourage and promote the use of enabling technologies for improving care coordination for beneficiaries. Specifically, such enabling technologies and services may include electronic health records and other health IT tools (such as population health management and data aggregation and analytic tools), telehealth services, remote patient monitoring, health information exchange services, or other electronic tools to engage patients in their care. We note that in section II.F. of this final rule we consider payment rule waivers for such things as telehealth services.

Additionally, we are finalizing our proposal to add a new provision at § 425.112(b)(4)(ii)(D) to require the applicant to describe how the ACO intends to partner with long-term and post-acute care providers to improve care coordination for the ACO's assigned beneficiaries. We note that in section II.F.7. of this final rule we discuss and finalize a waiver of the SNF 3-day rule.

Finally, based on comments, we will not finalize our proposal to add a provision under § 425.112(b)(4)(ii)(E) to require that an ACO define and submit major milestones or performance targets that it will use in each performance year to assess the progress of its ACO participants in implementing the elements required under § 425.112(b)(4). Although this requirement is not being finalized, ACOs are currently required under § 425.112(b)(4), as a condition of program eligibility and participation, to “define, establish, implement, evaluate, and periodically update” processes to

promote care coordination among primary care physicians, specialist, and acute and post-acute providers and suppliers. We believe that the obligation to evaluate such processes necessarily entails an evaluation of the ACO's progress in achieving care coordination.

9. Transition of Pioneer ACOs Into the Shared Savings Program

a. Overview

The Center for Medicare and Medicaid Innovation (the CMS Innovation Center) was established by section 1115A of the Act (as added by section 3021 of the Affordable Care Act) for the purpose of testing “innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care” for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits. The Pioneer ACO Model is a CMS Innovation Center initiative designed for organizations with experience operating as ACOs or in similar arrangements. Among the design elements being tested by the Pioneer ACO Model is the impact of using two-sided risk and different payment arrangements in to achieve the goals of providing better care to patients, and reducing Medicare costs. Under section 1899(b)(4) of the Act, to be eligible to participate in the Shared Savings Program, a provider of services or supplier may not also be participating in a program or demonstration project that involves shared savings, such as the Pioneer ACO Model. Thus, Pioneer ACOs are not permitted to participate concurrently in the Shared Savings Program. As Pioneer ACOs complete the model test (the agreement is for a minimum of 3 years with an option to participate for an additional 2 years), they would have an opportunity to transition to the Shared Savings Program. We believe it would be appropriate to establish an efficient process to facilitate this transition in a way that minimizes any unnecessary burdens on these ACOs and on CMS.

b. Proposed Revisions

In order to do this, we proposed to use a transition process that is similar to the transition process we established previously for Physician Group Practice (PGP) demonstration participants applying to participate in the Shared Savings Program. The PGP demonstration, authorized under section 1866A of the Act, was our first experience with a shared savings program in Medicare and served as a

model for many aspects of the Shared Savings Program.

In the November 2011 final rule (76 FR 67834), we finalized § 425.202(b), which provides that PGP sites applying for participation in the Shared Savings Program will be given the opportunity to complete a condensed application form. This condensed application form requires a PGP site to provide the information that was required for the standard Shared Savings Program application but that was not already obtained through its application for or via its participation in the PGP demonstration. Also, a PGP participant would be required to update any information contained in its application for the PGP demonstration that was also required on the standard Shared Savings Program application. Former PGP participants qualified to use a condensed application form if their ACO legal entity and TINs of ACO participant were the same as those that participated under the PGP demonstration.

We noted that, as we continue to implement the Shared Savings Program, we will likely have a similar situation with regard to Pioneer ACOs that have completed their current agreement and wish to transition to the Shared Savings Program. Given that we have been working with and have a level of familiarity with these organizations similar to that with the PGP participants, we stated our belief that it was appropriate to consider offering some latitude with regard to the process for applying to the Shared Savings Program for these ACOs.

Thus, we proposed to revise § 425.202(b) to offer Pioneer ACOs the opportunity to apply to the Shared Savings Program using a condensed application if three criteria are satisfied. First, the applicant ACO must be the same legal entity as the Pioneer ACO. Second, all of the TINs on the applicant's ACO participant list must have appeared on the "Confirmed Annual TIN/NPI List" (as defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO's last full performance year in the Pioneer ACO Model. Third, the applicant must be applying to participate in a two-sided model. We noted that, consistent with the statute and our regulation at § 425.114, any Pioneer ACO transitioning to the Shared Savings Program must apply to participate in the Shared Savings Program for an agreement period that would start after its participation in the Pioneer ACO Model has ceased. We further noted that Pioneer ACOs transitioning to the Shared Savings

Program would be subject to the standard program integrity screening and an evaluation of their history of compliance with the requirements of the Pioneer ACO Model.

Regarding the second criterion, we recognized that there are differences between the Pioneer ACO Model and the Shared Savings Program, and that only some of the NPIs within a TIN might have participated in the Pioneer ACO. Therefore, for purposes of determining whether a condensed application will be appropriate under the Shared Savings Program, we stated we would compare only the TINs and not NPIs. We also recognized that some TINs may not be able to obtain the consent of all NPIs billing through the TIN to participate in the Shared Savings Program, which disqualifies the TIN from participating in the program. Therefore, unlike with the PGP demonstration sites, we proposed to allow the ACO applicant to complete a condensed application form even if it drops TINs that participated in its Pioneer ACO. However, we proposed that if the applicant ACO includes TINs that were not on the Pioneer ACO's Confirmed Annual TIN/NPI List for its last full performance year in the Pioneer ACO Model, the applicant would be required to use the standard application for the Shared Savings Program. A Pioneer ACO applying to the Shared Savings Program using a condensed application form would be required to include a narrative description of the modifications they need to make to fulfill our requirements (for example, making changes to the governing body and obtaining or revising agreements with ACO participants and ACO providers/suppliers).

Because the Pioneer ACO Model is a risk-bearing model designed for more experienced organizations, the third proposed criterion would permit Pioneer ACOs to use the condensed application only if they apply to participate in the Shared Savings Program under a two-sided model. We established Track 1 of the Shared Savings Program as an on-ramp for ACOs while they gain experience and become ready to accept risk. In this case, the Pioneer ACOs are already experienced and will have already accepted significant financial risk. Therefore, under this proposal, former Pioneer ACOs would not be permitted to enter the Shared Savings Program under Track 1. We further noted that the rules and methodologies used under the Pioneer ACO Model to assess performance-based risk are different than under the Shared Savings Program. Therefore, we encourage former Pioneer

Model ACOs to carefully consider the risk-based track to which they apply under the Shared Savings Program, and to be cognizant of the differences in rules and methodologies.

We sought comments on this proposal to establish a condensed application process for Pioneer ACOs applying to participate in the Shared Savings Program and to require such Pioneer ACOs to participate under a track that includes performance-based risk. We noted that Pioneer ACOs that do not meet criteria for the condensed application would have to apply through the regular application process.

Comment: Commenters supported our proposal to revise § 425.202(b) to offer Pioneer ACOs the opportunity to apply to the Shared Savings Program using a condensed application. A commenter expressed concern that a transition to the Shared Savings Program might "disenfranchise both nurse practitioners and their patients" because of the statutory criterion that beneficiaries be assigned to Shared Savings Program ACOs based on primary care services rendered by physicians. Another commenter supported the proposals but recommended that CMS require Pioneer ACOs to complete a narrative detailing the modifications the ACO would make to comply with Shared Savings Program rules.

Response: We appreciate the support for our proposal to allow Pioneer ACOs to enter the Medicare Share Saving Program using a condensed application. We recognize there are differences between the Pioneer ACO Model and the Shared Savings Program requirements and methodologies, such as the assignment methodology, that may alter whether beneficiaries seen by certain provider types become assigned to a Shared Savings Program ACO. We believe that the commenter's concern regarding the differences in assignment methodologies and the "disenfranchisement" it may cause is not a sufficient reason to deny Pioneer ACOs the opportunity to use a condensed application when transitioning to the Shared Savings Program. Additionally, we intend to ensure that all applicants to the program are appropriately screened and meet eligibility requirements prior to participation, including applicants that may qualify to use a condensed application. As stated previously, the condensed application form will require the Pioneer ACO to describe the modifications it will need to make to fulfill our requirements (for example, making changes to the governing body and obtaining or revising agreements

with ACO participants and ACO providers/suppliers).

Comment: A few commenters suggested that CMS alter the criterion that a Pioneer ACO may use a condensed application if the applicant ACO is the same legal entity as the entity that participated under the Pioneer ACO Model. These commenters suggested that the criterion should be revised so that a former Pioneer ACO may demonstrate that it is either the same legal entity or that the majority of its ACO participants would remain the same. Several commenters requested that the criteria be modified to require a full application only if there is a 50 percent or greater change in the TIN makeup of the ACO. Another commenter recommended elimination of this criterion but did not provide details for the reason.

Response: We appreciate the suggestion; however, we believe the best way to determine if the organization is the same entity that is transitioning to the Shared Savings Program from the Pioneer ACO Model is to establish that its legal entity has the same TIN. As articulated by commenters in response to our proposal under § 425.214(a) to quantify a significant change in the ACO participant list, a simple percent threshold does not necessarily identify a 50 percent change, and a majority change could easily occur with the addition or removal of a very small number of TINs if the ACO is small. Similarly, we believe assessing whether the organization is the same on the basis of a percentage of a consistent cohort of ACO participant TINs is problematic. Therefore, we will finalize the criterion that a Pioneer ACO may use a condensed application if the applicant ACO is the same legal entity as the entity that participated under the Pioneer ACO Model.

Comment: Several commenters suggested CMS either eliminate or modify the criterion that in order to qualify to use the condensed application, all TINs on the applicant's ACO participant list must have appeared on the "Confirmed Annual TIN/NPI List" (as defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO's last full performance year in the Pioneer ACO Model. A few commenters suggested that Pioneer ACOs should be allowed to also include any TINs that they planned to add midyear (that is, during the application period). Several commenters supported comparing only ACO participant TINs and not ACO provider/supplier (NPI) lists because of the different rules under the two initiatives.

Response: We agree with commenters that supported the proposal to compare only TINs and not NPIs when assessing the ability of a Pioneer ACO that seeks to use a condensed application when transitioning to the Shared Savings Program. As we noted in the proposed rule, we recognized that there are differences between the Pioneer ACO Model and the Shared Savings Program, and that only some of the NPIs within a TIN might have participated in the Pioneer ACO. Therefore, for purposes of determining whether a condensed application will be appropriate under the Shared Savings Program, we stated we would compare only the TINs and not NPIs. We also recognized that some TINs may not be able to obtain the consent of all NPIs billing through the TIN to participate in the Shared Savings Program, which disqualifies the TIN from participating in the program. Therefore, unlike with the PGP demonstration sites, we proposed to allow the ACO applicant to complete a condensed application form even if it drops TINs that participated in its Pioneer ACO. While we understand the desire for organizations to annually update the ACO participants list, we have concerns that that permitting an ACO to add TINs during the application cycle during its transition to the Shared Savings Program would erode our ability to determine if the ACO closely approximates the same organization that is currently participating in the Pioneer ACO Model and thus its ability to qualify for using a condensed application. We welcome such ACOs to apply through the normal application process which permits both additions and deletions to the ACO participant list during the course of application review.

Comment: Many commenters strongly encouraged CMS not to define which track the applicant ACO must enter. Commenters suggested that although a Pioneer ACO participated in the more "advanced" program, there are different program rules in the Shared Savings Program. Additionally, a Pioneer ACO transitioning to the Shared Savings Program may not have been comfortable with the risk levels taken in Pioneer ACOs and may believe it should have the opportunity to move into a lower risk track.

Response: We clarify that we are not defining what track a transitioning Pioneer ACO must enter. Instead, we are offering the opportunity, when certain criteria are met, for such organizations to seamlessly transition to the Shared Savings Program using a condensed application, similar to the application offered to PGP demonstration sites as they transitioned from the PGP

demonstration to the Shared Savings Program. We believe these criteria are necessary and important to provide us with some assurance that the organization that is participating in the Pioneer ACO Model will be the same organization that will participate in the Shared Savings Program. We note that several former Pioneer ACOs that participated in the early years of the model were not comfortable with the increased risk that was phased in under the model after terminating their participation in the model; they used the normal application process to enter the Shared Savings Program under Track 1. We clarify that our proposal to use a condensed application was intended to assist Pioneer ACOs that are currently participating in the Pioneer ACO Model to transition seamlessly to the Shared Savings Program. We acknowledge that there are methodological differences between the two initiatives; however, because the Pioneer ACOs are currently participating in the model under performance-based two-sided risk, we do not believe such entities should be permitted to apply under Track 1. We recognize that such entities may wish to modify aspects of their organization, such as adding or removing certain Medicare-enrolled TINs from participation, or for other reasons may no longer be comfortable continuing to take two-sided risk. Such entities may not meet criteria for completing a condensed application or could choose to apply to the program through the normal application process. Such ACOs would then have the opportunity to elect to participate under Track 1. We also note that, similar to the process for offering PGP demonstration sites the opportunity to transition to the Shared Savings Program using a condensed application, we anticipate that this opportunity would be time-limited. In other words, because the Pioneer ACO Model is scheduled to end after next year, we anticipate that the only organizations transitioning would be those that apply in the summer of 2015 for a 2016 start date and those that apply in the summer of 2016 for a 2017 start date.

FINAL ACTION: We are finalizing and clarifying our proposal to use a transition process that is similar to the transition process we established previously for Physician Group Practice (PGP) demonstration participants applying to participate in the Shared Savings Program.

Specifically we are finalizing our proposal to revise § 425.202(b) to offer Pioneer ACOs the opportunity to apply to the Shared Savings Program using a

condensed application if certain criteria are satisfied. First, the applicant ACO must be the same legal entity as the Pioneer ACO. Second, all of the TINs on the applicant's ACO participant list must have appeared on the "Confirmed Annual TIN/NPI List" (as defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO's last full performance year in the Pioneer ACO Model. Third, the applicant must be applying to participate in a two-sided model. We note that, consistent with the statute and our regulation at § 425.114, any Pioneer ACO transitioning to the Shared Savings Program must apply to participate in the Shared Savings Program for an agreement period that would start after its participation in the Pioneer ACO Model has ceased. We further note that Pioneer ACOs transitioning to the Shared Savings Program would be subject to the standard program integrity screening and an evaluation of their history of compliance with the requirements of the Pioneer ACO Model.

C. Establishing and Maintaining the Participation Agreement With the Secretary

1. Background

The November 2011 final rule established procedures for applying to participate in the Shared Savings Program, including the need to submit a complete application, the content of the application, and our criteria for evaluating applications (see §§ 425.202 through 425.206). In addition, § 425.212 specifies which changes to program requirements will apply during the term of an ACO's participation agreement. In this section we discuss our proposals to clarify and to supplement the rules related to these requirements.

The current regulations address certain issues with respect to ACOs that wish to reapply after termination or experiencing a loss during their initial agreement period (§§ 425.222 and 425.600(c), respectively). However, the regulations are silent with respect to the procedures that apply to ACOs that successfully complete a 3-year agreement and would like to reapply for a subsequent agreement period in the Shared Savings Program. In this section, we discuss our proposal to establish the procedure for an ACO to renew its participation agreement for a subsequent agreement period.

2. Application Deadlines

a. Overview

To obtain a determination on whether a prospective ACO meets the

requirements to participate in the Shared Savings Program, our rules at § 425.202(a) require that an ACO submit a complete application in the form and manner required by CMS by the deadline established by CMS. Information on the required content of applications can be found in § 425.204, as well as in guidance published at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Application.html>. Among other requirements, applications must include certain information such as an ACO's prior participation in or termination from the program (§ 425.204(b)); documents such as participation agreements, employment contracts and operating policies (§ 425.204(c)(1)(i)); and a list of all ACO participants and their Medicare-enrolled TINs (§ 425.204(c)(5)(i)).

We determine and publish in advance on our Web site the relevant due dates for the initial submission of applications for each application cycle. While we expect ACOs to submit a completed application by the initial application due date specified on our Web site, we recognize that there may be portions of the application where additional information is necessary for CMS to make a determination. Therefore, according to § 425.206(a)(2), we notify an applicant when additional information is needed and provide an opportunity to submit information to complete the application by a deadline specified by CMS in the notice.

As stated in § 425.206(a), CMS evaluates an ACO's application on the basis of the information contained in and submitted with the application. Applications that remain incomplete after the deadline specified by CMS are denied. It is incumbent upon the ACO applicant to submit timely the information that is required for CMS to decide whether the applicant is eligible to participate in the program.

Finally, under § 425.202(c), CMS determines whether an applicant satisfies the requirements and is qualified to participate in the Shared Savings Program.

b. Proposed Revisions

In implementing the Shared Savings Program, we found that some applicants misunderstood our application process and the need to submit all required information by a specified deadline for submission of applications and supporting information. Thus, we proposed to revise our application review process set forth at § 425.206(a) to better reflect our review procedures.

We proposed to consolidate at § 425.206 two similar provisions regarding application review. Currently, § 425.202(c)(1) regarding application review provides that CMS determines whether an applicant satisfies the requirements of part 425 and is qualified to participate in the Shared Savings Program, and § 425.202(c)(2) provides that CMS approves or denies applications accordingly. We proposed to amend § 425.206(a)(1) to address the concept of application review currently set forth at § 425.202(c)(1), and we proposed to amend § 425.202(c) by replacing the existing text with language clarifying that CMS reviews applications in accordance with § 425.206.

We also proposed to revise § 425.206(a) to better reflect our application review process and the meaning of the reference to "application due date." Specifically, we proposed to revise § 425.206(a)(1) to clarify that CMS approves or denies an application on the basis of the following:

- Information contained in and submitted with the application by a deadline specified by CMS.
- Any supplemental information submitted in response to CMS' request for information and by a deadline specified by CMS.
- Other information available to CMS (including information on the ACO's program integrity history).

In addition, we proposed to amend § 425.206(a)(2) to clarify our process for requesting supplemental information and to add a new paragraph (a)(3) to specify that CMS may deny an application if an ACO applicant fails to submit supplemental information by the deadlines specified by CMS. We believe that additional clarity may result in more timely submission of the information necessary to evaluate applications. Moreover, it is critical that ACOs submit information on a timely basis so that we can perform other necessary operational processes before the start of the approved ACO's first performance year (for example, determining the number of beneficiaries assigned to the ACO, screening prospective ACO participants and ACO providers/suppliers, identifying the preliminary prospective list of assigned beneficiaries, and calculating the ACO's historical benchmark).

Comment: A few commenters supported our proposed changes as written. One of the commenters stated that it is important for ACOs to have definitive deadlines, and requested that CMS make clear all deadlines necessary for ACOs to meet all program

requirements, for example, deadlines for making public certain information.

Response: We agree with commenters that it is important to clearly communicate deadlines to ACOs. Specific application deadlines will continue to be posted on our Web site on an annual basis, and deadlines for the submission of supplemental information provided in response to a CMS' request will be communicated directly with applicants throughout the application review process. For ACOs that have been accepted into the program, we make announcements directly to ACOs through our weekly newsletter and the ACO's CMS coordinator. Deadlines are also indicated in guidance documents and the calendar posted on the ACO portal.

FINAL ACTION: We are finalizing our proposal to consolidate at § 425.206(a)(1) two similar provisions regarding application review found at § 425.202(c)(1) and § 425.202(c)(2). Therefore, we are finalizing our proposals to revise § 425.206(a)(1) to clarify that CMS approves or denies an application on the basis of the following:

- The information contained in and submitted with the application by the deadline.
- Any supplemental information submitted in response to a CMS request and by the specified deadline.
- Other information available to CMS (including information on the ACO's program integrity history).

Since incomplete applications prevent us from making a timely evaluation of whether the ACO satisfies the requirements of our regulations, we are also finalizing as proposed the policies related to application procedures and deadlines. Specifically, we are finalizing our proposals to amend § 425.206(a)(2) to clarify our process for requesting supplemental information and to add a new paragraph (a)(3) to specify that CMS may deny an application if an ACO applicant fails to submit information by the deadlines specified by CMS.

3. Renewal of Participation Agreements

a. Overview

For ACOs that would like to continue participating in the Shared Savings Program after the expiration of their current agreement period, we proposed a process for renewing their existing participation agreements, rather than requiring submission of a new or condensed application for continued program participation. Specifically, we proposed to add new § 425.224 to establish procedures for renewing the

participation agreements of ACOs. In addition, we proposed (in section II.C.4. of the proposed rule) to modify the definition of "agreement period" at § 425.20 to clarify its meaning in the context of participation agreement renewals.

b. Proposed Revisions

Under proposed § 425.224(a), an ACO would be permitted to request renewal of its participation agreement prior to its expiration in a form and manner and by a deadline specified by CMS in guidance. We proposed that an ACO executive who has the authority to legally bind the ACO must certify that the information contained in the renewal request is accurate, complete, and truthful. Further, we proposed that an ACO that seeks renewal of its participation agreement and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of its renewal request with the Antitrust Agencies (as defined at § 425.20). We anticipated that our operational guidance will outline a process permitting renewal requests during the last performance year of an ACO's participation agreement. For example, we stated that an ACO with a participation agreement ending on December 31, 2015 would be offered the opportunity to renew its participation agreement sometime during the 2015 calendar year in preparation to begin a new 3-year agreement period on January 1, 2016. To streamline program operations, we anticipated specifying a timeframe for submission and supplementation of renewal requests that would coincide with the deadlines applicable to submission and supplementation of applications by new ACO applicants under § 425.202.

Under proposed § 425.224(b), we proposed to evaluate an ACO's participation agreement renewal based on all of the following factors:

- Whether the ACO satisfies the criteria for operating under the selected risk model.
- The ACO's history of compliance with the requirements of the Shared Savings Program.
- Whether ACO established that it is in compliance with the eligibility and other requirements of the Shared Savings Program, including the ability to repay losses, if applicable.
- Whether the ACO met the quality performance standards during at least 1 of the first 2 years of the previous agreement period.
- Whether an ACO under a two-sided model repaid losses owed to the program that it generated during the

first 2 years of the previous agreement period.

- The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.304(b)).

We solicited comments on these criteria and any additional criteria that would help ensure the success of the program.

We further proposed to approve or deny a renewal request based on the information submitted in the request and other information available to CMS. We proposed to notify the ACO when the initial request is incomplete or inadequate and to provide an opportunity for the ACO to submit supplemental information to correct the deficiency. Under the proposal, the ACO must submit both the renewal request and any additional information needed to evaluate the request in the form and manner and by the deadlines specified by CMS.

Under § 425.224(c), we proposed to notify each ACO in writing of our determination to approve or deny the ACO's renewal request. If we were to deny the renewal request, the notice would specify the reasons for the denial and inform the ACO of any rights to request reconsideration review in accordance with the procedures specified in part 425 subpart I.

We stated our belief that a simple renewal process would reduce the burden for ACOs that wish to continue in the program and minimize the administrative burden on CMS, which would allow us to focus our attention on new applicants that have not yet established their eligibility to participate. We stated our intention to establish the deadlines and other operational details for this renewal process through guidance and instructions. Finally, we noted that under our proposal to modify the definition of the participation "agreement period" (section II.C.4 of this final rule), a new agreement period would begin upon the start of the first performance year of the renewed participation agreement.

Comment: A few stakeholders expressed support for our efforts to develop a renewal process. A commenter stated that the proposed criteria were appropriate and adequate to ensure the success of the program and to reduce the administrative burden on CMS and ACOs. Some offered specific comments related to the criteria for permitting an ACO to renew its agreement. For example, some commenters agreed that the renewal process should review the ACO's

history of compliance and quality performance. Some commenters suggested that CMS consider additional criteria for renewing current agreements, including the following:

- The stability of leadership.
- Attainment of certain levels of EHR implementation or accreditation.
- Establishment of a partnership with Geriatric Workforce Enhancement Programs.
- Other criteria related to the ACO's ability to perform utilization review and accept performance-based risk.

A commenter recommended that an ACO changing its legal entity or undergoing substantial changes in its ACO participant list be permitted to use the renewal application, rather than having to submit an application as a new ACO applicant.

Response: We agree with the commenters regarding the advantages of providing a more flexible renewal process for current ACOs who meet our specific criteria. We appreciate the support for our proposed renewal criteria and the suggested criteria; however, we do not believe that additional criteria are necessary at this time. As stated in the proposed rule, we believe the criteria as proposed will both ensure continued compliance with program rules and reduce the burden for ACOs that wish to continue in the program and minimize the administrative burden on CMS, which will allow us to focus our attention on new applicants that have not yet established their eligibility to participate. We clarify that ACOs seeking to renew agreements must be entities that have previously participated in the Shared Savings Program. In other words, the same legal entity that previously participated in the program may renew its agreement for a subsequent agreement period. New organizations that have not previously participated in the Shared Savings Program may apply using the established application process. We believe it is important to conduct a complete review of any new legal entity that wishes to apply for participation in the program.

FINAL ACTION: We are finalizing our policies as proposed regarding the renewal process. Specifically, we are finalizing our proposal to add new § 425.224 to establish procedures for renewal of the participation agreements of ACOs. Under § 425.224(a), an ACO will be permitted to request renewal of its participation agreement prior to its expiration in a form and manner and by a deadline specified by CMS in guidance. An ACO executive who has the authority to legally bind the ACO

must certify that the information contained in the renewal request is accurate, complete, and truthful. Further, an ACO that seeks renewal of its participation agreement and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of its renewal request with the Antitrust Agencies. To streamline program operations, we anticipate specifying in guidance a timeframe for submission and supplementation of renewal requests that will coincide with the deadlines applicable to submission and supplementation of applications by new ACO applicants under § 425.202.

Under § 425.224(b), CMS will evaluate an ACO's participation agreement renewal based on all of the following factors:

- Whether the ACO satisfied the criteria for operating under the selected risk model.
- The ACO's history of compliance with the requirements of the Shared Savings Program.
- Whether the ACO established that it is in compliance with the eligibility and other requirements of the Shared Savings Program, including the ability to repay losses, if applicable.
- Whether the ACO met the quality performance standards during at least 1 of the first 2 years of the previous agreement period.
- Whether an ACO under a two-sided model repaid losses owed to the program that it generated during the first 2 years of the previous agreement period.
- The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.304(b)).

CMS approves or denies a renewal request based on the information submitted in the request and other information available to CMS and notifies the ACO when the request is incomplete or inadequate to provide an opportunity for the ACO to submit supplemental information to correct the deficiency. The ACO must submit both the renewal request and any additional information needed to evaluate the request in the form and manner and by the deadlines specified by CMS.

Under § 425.224(c), we are finalizing our proposal to notify each ACO in writing of our determination to approve or deny the ACO's renewal request. If we deny the renewal request, the notice will specify the reasons for the denial and inform the ACO of any rights to request reconsideration review in accordance with the procedures specified in part 425 subpart I.

4. Changes to Program Requirements During the 3-Year Agreement

a. Overview

In the November 2011 final rule (76 FR 67838), we recognized the potential for changes to the Shared Savings Program regulations that would become effective while participating ACOs are in the middle of an agreement period. Therefore, we promulgated a rule to specify under what conditions an ACO would be subject to regulatory changes that become effective after the start of its agreement period. Specifically, we finalized § 425.212(a)(2), which provided that ACOs are subject to all regulatory changes with the exception of changes to the eligibility requirements concerning ACO structure and governance, the calculation of the sharing rate, and the assignment of beneficiaries. We did not exempt ACOs from becoming immediately subject to other regulatory changes. For example, we did not exempt changes such as those related to quality measures because of our belief that requiring ACOs to adhere to changes related to quality measures would ensure that they keep pace with changes in clinical practices and developments in evidence-based medicine.

The November 2011 final rule did not require ACOs to be subject to any regulatory changes regarding beneficiary assignment that become effective during an agreement period because we recognized that changes in the beneficiary assignment methodology could necessitate changes to ACOs' financial benchmarks. At the time we published the November 2011 final rule (76 FR 67838), we had not developed a methodology for adjusting an ACO's benchmark to reflect changes in the beneficiary assignment methodology during an agreement period. We anticipated that ACOs would complete their 3-year agreement period with a relatively stable set of ACO participants. Therefore, they would all have stable benchmarks during the 3-year agreement period that would require updates only to reflect annual national FFS trends and changes in beneficiary characteristics, consistent with statutory requirements. Without a methodology for adjusting benchmarks to reflect changes in the beneficiary assignment methodology during the agreement period, we were reluctant to subject ACOs to immediate regulatory changes that could impact their benchmarks during the term of a participation agreement. However, in light of the extensive changes ACOs made to their lists of ACO participants during the first 2 performance years, the significant

effect these changes had upon beneficiary assignment, and our subsequent development of policies regarding benchmark adjustment at the start of each performance year to reflect such changes (see <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html>), we proposed to revise the types of regulatory changes an ACO would become subject to during its agreement period. We also proposed to clarify § 425.212(a) regarding the applicability of certain regulatory changes and to clarify the definition of “agreement period” under § 425.20.

b. Proposed Revisions

We proposed to modify § 425.212(a) to provide that ACOs are subject to all regulatory changes “that become effective during the agreement period,” except for regulations regarding certain specified program areas (specifically, the eligibility requirements concerning the structure and governance of ACOs and calculation of the sharing rate), “unless otherwise required by statute.” This proposed revision corrects the omission of temporal language in the requirement regarding regulatory changes. In addition, it clarifies that ACOs would be subject to regulatory changes regarding ACO structure and governance, and calculation of the sharing rate during an agreement period if CMS is mandated by statute to implement such changes by regulation in the middle of a performance year.

In addition, we proposed to modify the definition of “agreement period” at § 425.20. The term “agreement period” is currently defined at § 425.20 to mean “the term of the participation agreement which begins at the start of the first performance year and concludes at the end of the final performance year.” However, in light of our proposal to renew participation agreements (see section II.C.3. of this final rule), the reference to “final performance year” in the existing definition is ambiguous. For example, if the “final performance year” of the agreement period includes the last performance year of a renewed participation agreement, an ACO would never be subject to regulatory changes regarding ACO structure and governance or calculation of the sharing rate. Therefore, we proposed to amend the definition to provide that the agreement period would be 3-performance years, unless otherwise specified in the participation agreement. Thus, an ACO whose participation agreement is renewed for a second or subsequent agreement period would be subject, beginning at the start of that

second or subsequent agreement period, to any regulatory changes regarding ACO structure and governance that became effective during the previous 3 years (that is, during the preceding agreement period).

Also, we proposed to require ACOs to be subject to any regulatory changes regarding beneficiary assignment that become effective during an agreement period. Specifically, we proposed to remove beneficiary assignment as an exception under § 425.212(a). Consistent with our authority under section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark “for beneficiary characteristics and other factors as the Secretary determines appropriate,” we have now developed operational policies under which we are able to adjust the benchmark on a yearly basis to account for changes in beneficiary assignment resulting from changes in the ACO’s list of ACO participants. For more detailed information on these policies see <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Updating-ACO-Participant-List.html>. Given that these operational policies enable annual adjustments to ACO benchmarks to account for changes in beneficiary assignment resulting from changes in ACO participants, we believe we would also be able to adjust an ACO’s benchmark to account for regulatory changes regarding beneficiary assignment methodology that become effective during an agreement period. Accordingly, we do not believe our proposal to make regulatory changes regarding beneficiary assignment applicable to ACOs during an agreement period would inappropriately affect the calculation of an ACO’s benchmark or shared savings for a given performance year. Rather, our adjustment methodology will ensure continued and appropriate comparison between benchmark and performance year expenditures.

Under this proposal, regulatory changes regarding beneficiary assignment would apply to all ACOs, including those ACOs that are in the middle of an agreement period. However, as discussed in section II.E.6. of this final rule, we also proposed that any final regulations that affect beneficiary assignment would not be applicable until the start of the next performance year. We believe that implementing any revisions to the assignment methodology at the beginning of a performance year is reasonable and appropriate because it would permit time for us to make the necessary programming changes and would not disrupt the assessment of

ACOs for the current performance year. Moreover, we would adjust all benchmarks at the start of the first performance year in which the new assignment rules are applied so that the historical benchmark for an ACO reflects the use of the same assignment rules that would apply in the performance year.

We also noted that we would carefully consider the timing and effect on both current and future ACOs of any new regulatory proposal, and when promulgating new regulatory changes through rulemaking, we would solicit comment on these matters. Additionally, when implementing a final rule that changes our processes and methodologies, we stated that we would alert current and prospective ACOs of such changes via CMS communications and updates to guidance.

Comment: A commenter recommended a uniform start of January 1 of the year following changes in regulations to allow ACOs to adequately plan, budget, recruit, and make the necessary staffing adjustments to meet new requirements. Another commenter suggested that CMS proceed cautiously when making regulatory changes that would impact an ACO in the middle of an agreement period. Finally, another commenter recommended that CMS permit ACOs to exit the MSSP during a performance year if the ACO believes the regulatory changes are detrimental to the ACO’s performance goals.

Response: We appreciate the comments regarding regulatory changes and their impact on ACOs that are currently participating in the program. We agree with stakeholders that January 1 of a performance year is a logical time to make regulatory changes effective for beneficiary assignment. We also agree that regulatory changes that impact ACOs during an agreement should be considered carefully, and the rulemaking process will provide ACOs with an opportunity to comment on the effective date for such changes. Finally, we note that an ACO is permitted under § 425.212(d) to terminate its participation agreement in those instances where statutory or regulatory standards are established during the agreement period which the ACO believes will impact its ability to continue participating in the Shared Savings Program.

Comment: A few commenters agreed with our proposed revision of the definition of an agreement period as written. Several commenters specifically supported the revision because they believe this would give CMS flexibility to extend the agreement

period from three to five years as discussed in greater detail in section II.F.2. of this final rule.

Response: We appreciate the support for the revision to the definition of an agreement period and will finalize as proposed. As further discussed in section II.F.3. of this final rule, we do not at this time intend to extend the term of an ACO's agreement period. In accordance with § 425.200(b)(2)(ii), the term of the agreement period is three years for ACOs that are approved to participate in the Shared Savings Program for 2013 and all subsequent years.

FINAL ACTION: We are finalizing our policies as proposed. Specifically, we are finalizing our modification of § 425.212(a) to provide that ACOs are subject to all regulatory changes "that become effective during the agreement period," except for regulations regarding certain specified program areas, "unless otherwise required by statute." This proposed revision corrects the omission of temporal language in the requirement regarding regulatory changes and clarifies that ACOs are subject to regulatory changes regarding ACO structure and governance, and calculation of the sharing rate during an agreement period if CMS is mandated by statute to implement such changes by regulation in the middle of a performance year.

In addition, we are finalizing our modification of the definition of "agreement period" at § 425.20. Thus, an ACO whose participation agreement is renewed for a second or subsequent agreement period would be subject, beginning at the start of that second or subsequent agreement period, to any regulatory changes regarding ACO structure and governance that became effective during the previous 3 years (that is, during the preceding agreement period).

Also, we are finalizing our proposal to remove beneficiary assignment as an exception under § 425.212(a). Regulatory changes regarding beneficiary assignment will apply to all ACOs, including those ACOs that are in the middle of an agreement period. However, as discussed in section II.E.6. of this final rule, any final policies that affect beneficiary assignment will not apply until the start of the next performance year. We believe that implementing any revisions to the assignment methodology at the beginning of a performance year is reasonable and appropriate, because it will allow us to make the necessary programming changes and will not disrupt the assessment of ACOs for the current performance year. Moreover, we

will adjust all benchmarks at the start of the first performance year in which the new assignment rules are applied so that the historical benchmark for an ACO reflects the use of the same assignment rules that will apply in the performance year.

D. Provision of Aggregate and Beneficiary Identifiable Data

1. Background

Under section 1899(b)(2)(A) of the Act, an ACO must "be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it." Furthermore, in order to be eligible to participate in the Shared Savings Program, section 1899(b)(2)(G) of the Act states an "ACO shall define processes to . . . report on quality and cost measures, and coordinate care. . . ." However, section 1899 of the Act does not address what data, if any, we should make available to ACOs on their assigned beneficiary populations to support them in evaluating the performance of ACO participants and ACO providers/suppliers, conducting quality assessment and improvement activities, or conducting population-based activities relating to improved health.

As we explained in the November 2011 final rule (76 FR 67844), in agreeing to become accountable for a group of Medicare beneficiaries, and as a condition of participation in the Shared Savings Program, we expect that ACOs will have, or are working towards having, processes in place to independently identify and produce the data they believe are necessary to best evaluate the health needs of their patient population, improve health outcomes, monitor provider/supplier quality of care and patient experience of care, and produce efficiencies in utilization of services. Therefore, it is our expectation that ACOs are actively working on developing and refining these processes. Moreover, we continue to believe this ability to independently identify and produce data for evaluating, improving, and monitoring the health of their patient population is a critical skill for each ACO to develop, leading to an understanding of the patient population that it serves. Once the ACO achieves an understanding of its patient population, it can work toward redesigning appropriate care processes to address the specific needs of its patient population.

However, as we noted previously (76 FR 67844), while an ACO typically should have, or at least be moving towards having complete information

for the services its ACO providers/suppliers furnish to Medicare FFS beneficiaries, we recognize that the ACO may not have access to information about services provided to its assigned beneficiaries by health care providers and suppliers outside the ACO—information that may be key to the ACO's coordination of care efforts. Therefore, during the original rulemaking process for the Shared Savings Program, we proposed and made final a policy—

- To distribute aggregate-level data reports to ACOs;
- Upon request from the ACO, to share limited identifying information about beneficiaries who are preliminarily prospectively assigned to the ACO and whose information serves as the basis for the aggregate reports; and
- Upon request from the ACO, to share certain beneficiary identifiable claims data with the ACO to enable it to conduct quality assessment and improvement activities, care coordination, or both, on its own behalf as a covered entity, or on behalf of its ACO participants and ACO providers/suppliers that are covered entities, unless the beneficiary chooses to decline to share his or her claims data.

As we stated in the November 2011 final rule (76 FR 67844), we believe that access to beneficiary identifiable information would provide ACOs with a more complete picture about the care their assigned beneficiaries receive, both within and outside the ACO. In addition, it is our view that this information would help ACOs evaluate providers'/suppliers' performance, conduct quality assessment and improvement activities, perform care coordination activities, and conduct population-based activities relating to improved health.

In the April 2011 proposed rule (76 FR 19558), we described the circumstances under which we believe that the HIPAA Privacy Rule would permit our disclosure of certain Medicare Part A and B data to ACOs participating in the Shared Savings Program. Specifically, under the Shared Savings Program statute and regulations, ACOs are tasked with working with their ACO participants and ACO providers/suppliers to evaluate their performance, conduct quality assessment and improvement activities, perform care coordination activities, and conduct population-based activities relating to improved health for their assigned beneficiary population. When done by or on behalf of a covered entity, these are functions and activities that would qualify as "health care

operations” under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. As such, these activities can be done by an ACO either on its own behalf, if it is itself a covered entity, or on behalf of its covered entity ACO participants and ACO providers/suppliers, in which case the ACO would be acting as the business associate of its covered entity ACO participants and ACO providers/suppliers. Accordingly we concluded that the disclosure of Part A and B claims data would be permitted by the HIPAA Privacy Rule provisions governing disclosures for “health care operations,” provided certain conditions are met.

As we also discussed, upon receipt of a request for protected health information (PHI), a covered entity or its business associate is permitted to disclose PHI to another covered entity or its business associate for the requestor’s health care operations if both entities have or had a relationship with the subject of the records to be disclosed (which is true in the Shared Savings Program), the records pertain to that relationship (which is also true in the Shared Savings Program), and the recipient states in its request for the data that it plans to use the records for a “health care operations” function that falls within the first two paragraphs of the definition of “health care operations” in the HIPAA Privacy Rule and that the data requested are the “minimum necessary” to carry out those health care operations. (See, the HIPAA Privacy regulations at 45 CFR 164.502(b) and 164.506(c)(4)). The first two paragraphs of the definition of health care operations under 45 CFR 164.501 include evaluating a provider’s or supplier’s performance, conducting quality assessment and improvement activities, care coordination activities, and conducting population-based activities relating to improved health.

With respect to the relationship requirements in 45 CFR 164.506(c)(4), we have a relationship with the individuals who are the subjects of the requested PHI because they are Medicare beneficiaries. The ACO has a relationship with such individuals, either as a covered entity itself or on behalf of its covered entity ACO participants and ACO providers/suppliers as a business associate, because the individuals are either preliminarily prospectively assigned to the ACO or have received a primary care service during the past 12-month period from an ACO participant upon whom assignment is based. We note that when we refer to an ACO participant “upon whom assignment is based,” we are

referring to an ACO participant that submits claims for primary care service used to determine the ACO’s assigned population under 42 CFR part 425 subpart E. In addition, the requested PHI pertains to the individuals’ relationship with both CMS and the ACO, in that we provide health care coverage for Medicare FFS beneficiaries and have an interest in ensuring that they receive high quality and efficient care, and the ACO is responsible for managing and coordinating the care of these individuals, who are part of the ACO’s assigned beneficiary population.

Beneficiary identifiable Medicare prescription drug information could also be used by ACOs to improve the care coordination of their patient populations. Accordingly, consistent with the regulations governing the release of Part D data, in the April 2011 proposed rule (76 FR 19559), we also proposed to make available the minimum Part D data necessary to allow for the evaluation of the performance of ACO participants and ACO providers/suppliers, to conduct quality assessment and improvement, to perform care coordination, and to conduct population-based activities relating to improved health.

In the November 2011 final rule (76 FR 67846 and 67851), we adopted a policy that defined when we would share beneficiary identifiable information (including Part A and B claims data and Part D prescription drug event data) for preliminarily prospectively assigned beneficiaries and those beneficiaries who have a primary care visit with an ACO participant that is used to assign beneficiaries to the ACO. As a basic requirement, in order to receive such data an ACO that chooses to access beneficiary identifiable data is required under 42 CFR 425.704 to request the minimum data necessary for the ACO to conduct health care operations work, either as a HIPAA-covered entity in its own right, or as the business associate of one or more HIPAA-covered entities (where such covered entities are the ACO participants and ACO providers/suppliers), for “health care operations” activities that fall within the first or second paragraph of the definition of health care operations at 45 CFR 164.501. As part of their application to participate in the Shared Savings Program, ACOs certify whether they intend to request beneficiary identifiable information, and that the requested data reflects the minimum necessary for the ACO to conduct health care operations either on its own behalf or on behalf of its covered entity ACO participants and ACO provider/

suppliers. Thus, the ACO’s formal request to receive data is accomplished at the time of its application to the Shared Savings Program. The ACO must also enter into a data use agreement (DUA) with CMS. If all of these conditions are satisfied, CMS makes available certain limited PHI regarding the preliminarily prospectively assigned beneficiaries whose data were used to generate the aggregate data reports provided to the ACO under § 425.702(b) and other beneficiaries who have a primary care visit during the performance year with an ACO participant upon whom assignment is based. In order to enhance transparency and beneficiary engagement, we also finalized a policy that before ACOs may start receiving PHI in the form of beneficiary identifiable claims data, they must give beneficiaries the opportunity to decline sharing of their claims data as required under § 425.708.

As we stated in the proposed rule, since the publication of the November 2011 final rule, we have gained further experience with sharing data with ACOs participating in the Shared Savings Program. We explained in the proposed rule that we continue to believe that distributing aggregate reports, paired with making available certain beneficiary identifiable information related to preliminarily prospectively assigned beneficiaries, as well as making available the claims data for preliminarily prospectively assigned FFS beneficiaries and other FFS beneficiaries who have primary care service visits with ACO participants that submit claims for primary care services that are used to determine the ACO’s assigned population, is worthwhile and consistent with the goals of the Shared Savings Program. The aggregate data reports and the beneficiary identifiable information related to preliminarily prospectively assigned beneficiaries give ACOs valuable information that can be used to better understand their patient population, redesign care processes, and better coordinate the care of their beneficiaries. ACOs participating in the Shared Savings Program have reported that the beneficiary identifiable claims data that they receive from us are being used effectively to better understand the FFS beneficiaries who are served by their ACO participants and ACO providers/suppliers. These data give ACOs valuable insight into patterns of care for their beneficiary population; enable them to improve care coordination among and across providers and suppliers and sites of care, including providers and suppliers and sites of care

not affiliated with the ACO; and allow them to identify and address gaps in patient care.

However, based upon our experiences administering the Shared Savings Program and feedback from stakeholders, we stated in the proposed rule that we believe that we can improve our data sharing policies and processes to streamline access to such data to better support the overall program, ACO functions and goals, and to better serve Medicare beneficiaries. Therefore, we proposed a number of modifications to our data sharing policies and procedures under the Shared Savings Program.

We received several general comments about data sharing under the Shared Savings Program.

Comment: A commenter suggested that we engage with the HHS interoperability roadmap work currently underway to ensure that the needs for sharing and integration of high quality, timely and interoperable data needed to support ACO functions are addressed. Some commenters requested that CMS share with ACOs the same type and amount of data that is routinely shared with MA plans and with the same frequency; for example, some commenters requested that we provide information to ACOs when a beneficiary's Medicare eligibility is checked by a provider or supplier. Some commenters stated they believe that the assignment methodology should be modified because it is responsible for creating delays in the provision of data, including claims data, quarterly data, and annual performance data.

Response: As noted in the November 2011 final rule, we expect that ACOs will have, or will be working towards having, processes in place to independently identify and produce the data they believe are necessary to best evaluate the health needs of their patient population, improve health outcomes, monitor provider/supplier quality of care and patient experience of care, and produce efficiencies in utilization of services. We believe that with a robust health information exchange infrastructure and improved communication among ACO participants and the ACO's neighboring health care providers, ACOs will be better equipped to access data in a timeframe that is closer to "real time." Many ACOs are developing innovative solutions to share "real time" information across sites of care and are actively engaged, as are we, in the HHS-wide discussions currently underway.

However, we recognize that information from the CMS claims system could supplement an ACO's

understanding of its patient population. Although we understand that ACOs would like to obtain data as services are performed, as we explained in the April 2011 proposed rule (76 FR 19558), there is an inherent lag between when a service is performed and when the service is submitted for payment in FFS Medicare. Thus, our inability to provide data in real time to ACOs is not due to our methodology for assigning beneficiaries to ACOs, and ACOs participating in the Shared Savings Program are unlike managed care plans where preauthorization may be required for services. Although there is a mechanism by which external entities such as ACOs and providers can verify the Medicare enrollment status of a beneficiary through the HIPAA Eligibility Transaction System (HETS), our preliminary analysis suggests that the HETS eligibility checks through do not reliably predict what services or when, how, or by whom a service may be furnished to a beneficiary with FFS Medicare. Therefore, we believe the HETS information would be of limited value to an ACO.

Comment: A commenter requested that CMS make the data reports provided to ACOs available to independent researchers to support additional analysis of the impact of the Shared Savings Program.

Response: We recognize the public interest in obtaining this type of information. For this reason, we have made a set of Shared Savings Program research identifiable files available through the Research Data Assistance Center (ResDAC). To learn more about these files visit the ResDAC Web site: <http://www.resdac.org/news/shared-savings-program-aco-research-identifiable-files/2015/01-0>.

2. Aggregate Data Reports and Limited Identifiable Data

a. Overview

Under § 425.702, we share aggregate reports with ACOs at the beginning of the agreement period based on beneficiary claims used to calculate the benchmark, each quarter thereafter based on the quarterly assignment window, and in conjunction with the annual reconciliation. The aggregate reports provided under § 425.702(a) and (b) contain certain de-identified beneficiary information including all of the following:

- Aggregated metrics on the ACO's preliminarily prospectively assigned beneficiary population, including characteristics of the assigned beneficiary population, the number of primary care services provided to the

assigned beneficiary population by the ACO, and the proportion of primary care services provided to the assigned beneficiary population by ACO participants upon whom assignment is based.

- Expenditure data for the ACO's assigned beneficiary population by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) and type of service (for example, inpatient hospital, physician, etc.).

- Utilization data on select metrics for the assigned population, such as ambulatory care sensitive conditions discharge rates per 1,000 beneficiaries for conditions such as congestive heart failure (CHF), and utilization rates for imaging, emergency department visits, hospitalizations, and primary care services.

In addition, under § 425.702(c), we also provide a report that includes certain beneficiary identifiable information about the beneficiaries who are preliminarily prospectively assigned to the ACO and whose data were used to generate the de-identified aggregate data reports. The information currently contained in this assignment report includes the beneficiary name, date of birth, HICN, and sex. These beneficiary identifiable data are made available to an ACO that has met the conditions previously discussed in detail for purposes of carrying out population-based activities related to improving health or reducing growth in health care costs, process development (such as care coordination processes), case management, and care coordination for the beneficiary population assigned to the ACO. Under § 425.708(d) these data points are not subject to the requirement that an ACO give beneficiaries an opportunity to decline claims data sharing.

As we stated in the proposed rule, feedback we received since the November 2011 final rule was issued and during implementation of the Shared Savings Program, has confirmed there is a strong desire among ACOs and their ACO participants and ACO providers/suppliers to have as much information about their patients as is possible, in as timely a manner as possible, to better coordinate care and target care strategies toward individual beneficiaries. Moreover, ACOs are actively using the reports provided under § 425.702 to conduct their health care operations work with the expectation that it will result in higher quality and more efficient care for their assigned beneficiary populations. However, ACOs and their ACO participants and ACO providers/

suppliers have also reported that the four data elements currently made available on the assignment reports severely limit their care redesign efforts. They have indicated that additional data elements are necessary in order to conduct health care operations work under the first or second paragraph of the definition of health care operations at 45 CFR 164.501. For example, an ACO reported that having data not only on the frequency of hospitalizations but also on which specific beneficiaries were hospitalized and in which specific hospitals would better enable it to identify the effectiveness and outcomes of its post-hospitalization care coordination processes. Some stakeholders have made suggestions for beneficiary identifiable data that should be included in the quarterly reports in addition to the current four data elements, such as risk profiles or information on whether the beneficiary had a hospital visit in the past year. Some stakeholders suggested that the report be expanded to include information not only for the beneficiaries who received a plurality of their primary care services from ACO professionals, but also for all FFS beneficiaries who received a primary care service from an ACO participant in the past year. These stakeholders stated that understanding the entire FFS patient population served by the ACO and its ACO participants would improve their ability to redesign care, and reduce the uncertainty associated with a list of preliminarily prospectively assigned beneficiaries that fluctuates from quarter to quarter, based on the population's use of primary care services.

b. Proposed Revisions

In the proposed rule, we considered what additional beneficiary identifiable data might be the minimum necessary to support the ACOs' health care operations work. Based on our discussions with ACOs and ACO participants and ACO providers/suppliers, we explained our belief that making additional information available to ACOs about the FFS beneficiaries they serve, including for example, on whether a beneficiary visited an emergency room or was hospitalized, would help support such efforts. Thus, we proposed to expand the information made available to ACOs under § 425.702(c) to include certain additional beneficiary identifiable data subject to the existing requirements of § 425.702(c)(2), which incorporates the requirements under HIPAA governing the disclosure of PHI. Specifically, in addition to the four data elements

(name, date of birth, HICN, and sex) that we currently make available for preliminarily prospectively assigned beneficiaries, we proposed to expand the beneficiary identifiable information that is made available under existing § 425.702(c)(1) to include these data elements (name, date of birth, HICN, and sex) for each beneficiary who has a primary care service visit with an ACO participant that bills for primary care services that are considered in the assignment process in the most recent 12-month period.

Additionally, we proposed to expand the beneficiary identifiable information made available for preliminarily prospectively assigned beneficiaries to include additional data points. The information would be derived from the same claims used to determine the preliminary prospective assigned beneficiary list. Specifically, we proposed that we would make available the minimum data set necessary for purposes of the ACO's population-based activities related to improving health or reducing health care costs, required process development (under § 425.112), care management, and care coordination for its preliminarily prospectively assigned beneficiary population, at the following times:

- At the beginning of the agreement period.
- At the beginning of each performance year and quarterly thereafter.
- In conjunction with the annual reconciliation.

We stated that we would articulate the data elements associated with the minimum data set in operational guidance, and update as needed to reflect changes in the minimum data necessary for ACOs to perform these activities. The information would fall under the following categories:

- Demographic data such as enrollment status.
- Health status information such as risk profile, and chronic condition subgroup.
- Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including dates and place of service.
- Expenditure information related to utilization of services.

We explained our belief that under this approach the data made available in the aggregate data reports under § 425.702(c) would generally constitute the minimum data necessary for covered entity ACOs or for ACOs serving as the business associate of their covered entity ACO participants and ACO providers/suppliers, to evaluate

providers' and suppliers' performance, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health.

Finally, we noted in the proposed rule that these proposals for expansion of the data reports provided under § 425.702(c) to include each FFS beneficiary who has a primary care visit with an ACO participant that submits claims for primary care services that are considered in the assignment process, would apply only to ACOs participating in Tracks 1 and 2, where beneficiaries are assigned in a preliminarily prospective manner with retrospective reconciliation. This is because ACOs in Tracks 1 and 2 have an incentive to redesign care processes for all FFS beneficiaries who receive care from their ACO participants, due to the nature of the preliminarily prospective assignment methodology with retrospective reconciliation. Under our proposal for Track 3, which is discussed in detail in section II.F.3.a. of this final rule, we explained our belief that the minimum data necessary for ACOs to perform health care operations as defined under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501, would not extend beyond data needed for health operations related to the prospective list of assigned beneficiaries. We expressed our belief that a prospective assignment approach incentivizes targeting of the specific FFS beneficiaries on the list for care improvement, rather than redesigning care processes for all FFS beneficiaries seen by the ACO participants. As such, the minimum data necessary required for Track 3 ACOs to perform health care operations work would be limited to the data for beneficiaries who are prospectively assigned for a performance year. Thus, for Track 3, we proposed to limit the beneficiary identifiable data included in the reports made available under § 425.702(c) to only those beneficiaries who appear on the ACO's prospective list of beneficiaries at the beginning of a performance year. Specifically, under our proposal, Track 3 ACOs would have access to beneficiary identifiable data elements associated with the list of categories under § 425.702(c) for beneficiaries prospectively assigned to the ACO, but would not be able to request any information related to other Medicare FFS beneficiaries who receive primary care services that are considered in the assignment process from ACO participants. We explained our belief that this limitation was

reasonable because, under Track 3, the prospectively assigned beneficiary list would encompass all beneficiaries for whom the ACO would be held accountable in a given performance year, in contrast to ACOs in Tracks 1 and 2 that would be held accountable for any FFS beneficiaries who choose to receive a plurality of their primary care services from ACO professionals billing through the TINs of ACO participants.

We sought comment on our proposal to expand the data set made available to ACOs under § 425.702(c). We sought comment on the categories of information that we proposed to include and on any other beneficiary identifiable information that should be offered in the aggregate reports provided under § 425.702(c) in order to allow ACOs as covered entities or as the business associate of their covered entity ACO participants and ACO providers/suppliers to conduct health care operations work under paragraphs one or two of the definition of health care operations at 45 CFR 164.501. We also specifically sought comment on our proposal to expand the list of beneficiaries for which data are made available under § 425.702(c) to ACOs participating in Track 1 and Track 2 to include all beneficiaries who had a primary care service visit with an ACO participant that submits claims for primary care services that are considered in the assignment process. We received a number of comments on these proposals. In general, there was overwhelming support for our proposal to expand the beneficiary identifiable information that is made available under existing § 425.702(c)(1) to include name, date of birth, HICN, and sex for each beneficiary who has a primary care service visit with an ACO participant that bills for primary care services that are considered in the assignment process in the most recent 12-month period. However, there were also suggestions on how we might improve the structure, content, and provision of both the de-identified and beneficiary identifiable information in the aggregate data reports made available under § 425.702.

Comment: Many commenters supported the proposed expansion of the beneficiary identifiable data made available to ACOs in the aggregate data reports. Numerous commenters made specific requests to expand the information made available under § 425.702(b) and (c) to include various other identifiable and de-identified data elements, including but not limited to:

- Beneficiary demographic information, including contact information.

- Beneficiary eligibility information, including the date of the beneficiary's original Medicare eligibility and the date of any change in eligibility status.

- Aggregate information about the expenditures and utilization rates of claims that are missing from the claims files, for example, for beneficiaries who have declined claims data sharing.

- Health status data, such as Hierarchical Condition Category (HCC) scores for each beneficiary or quarterly analysis showing changes in beneficiaries' HCC scores.

- An indicator of the beneficiary's institutional/hospice status.

- Substance abuse expenditure data (in aggregate).

- Expanded utilization information for primary care versus non-primary care services.

- Information about ancillary services.

- Information from Part D pharmacy claims.

Response: We appreciate the commenters' support for our proposal to expand the data made available to ACOs and we are finalizing our policy as proposed. We also appreciate the commenters' thoughtful suggestions regarding additional data elements that should be made available under § 425.702(b) and (c). Many of the specific suggestions to expand the data elements available to ACOs are already covered in the four categories of information that we proposed to include: Demographic data, health status information, utilization rates, and expenditure information related to utilization of services. Therefore, we will consider commenters' suggestions as we determine the specific data points to include in our program reports. We will articulate the data elements associated with the minimum data set in operational guidance and update as needed to reflect changes in the minimum data necessary for ACOs to perform health care operations activities. However, we note that although we are finalizing our proposal to make available health status information, such as risk profile and chronic condition subgroup, at this time we do not intend to release beneficiary identifiable HCC risk score data to ACOs participating in the Shared Savings Program because this is not information that CMS has historically shared through the MA program or any other model or demonstration. We believe that providing the risk profile and chronic condition subgroups associated with a beneficiary will be more helpful to ACOs in identifying higher acuity beneficiaries and beneficiaries with multiple chronic conditions that could

benefit from more intensive care coordination. We note that receiving this information would not preclude an ACO from calculating HCC risk scores based on its own claims data and publicly available software. We also do not intend to release contact information for individual beneficiaries. As we are eliminating the option for ACOs to notify beneficiaries by mail regarding the opportunity to decline data sharing, we believe there is no need for CMS to share beneficiary contact information with ACOs.

Comment: Many commenters requested that we expand the availability of beneficiary identifiable data under § 425.702(c) to Track 3 ACOs beyond the list of beneficiaries prospectively assigned to the ACOs. Some commenters suggested that prospective assignment be applied to all three tracks, which would obviate the need to distribute information beyond this list. A commenter suggested that we include on the reports under § 425.702(c) beneficiaries who have had a primary care service visit with an ACO participant used in the assignment methodology within the past 24 months, instead of the previous 12 months.

Response: In section II.F.3. of this final rule, we are finalizing our proposal to assign beneficiaries prospectively to Track 3 ACOs. As discussed previously, we believe the minimum data necessary for Track 3 ACOs to perform health care operations as defined under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501 would not extend beyond data needed for health care operations related to the prospective list of assigned beneficiaries because the prospective assignment list would encompass all beneficiaries for whom the ACO would be held accountable in a given performance year. Therefore, we will limit the information provided under § 425.702(c)(1)(ii)(A) and (c)(1)(ii)(B) to the Track 3 ACO's list of prospectively assigned beneficiaries. In addition, we believe it is important to provide information to ACOs participating in Tracks 1 and 2 about beneficiaries who have had at least one primary care service visit with an ACO participant that is used in the assignment methodology because, at the time of retrospective reconciliation, the ACO may be determined responsible for their care during the performance year. We believe a 12 month look-back is sufficient for these purposes, but we may revisit this issue in future rulemaking.

Comment: Many commenters requested that we provide detailed documentation regarding the definition

and calculation of each of the metrics in the reports provided under § 425.702(b) and examples of how these metrics can be calculated from the Claim and Claim Line Feed (CCLF) files. Commenters requested that we make available these calculations and examples to new ACOs prior to their start date in the Shared Savings Program. A commenter recommended that we use open source methods for all data and calculations in the Shared Savings Program. Another commenter suggested providing Shared Savings Program ACOs with the same summary reports given to Pioneer ACOs. Several commenters requested that we provide the aggregate reports under § 425.702 to ACOs in a user-friendly format or more often—for example, monthly. Several commenters requested that the quarterly reports include an update to the ACO's benchmark based on changing HCC scores and enrollment mix relative to the benchmark period.

Response: We recognize that certain reports provided under the Shared Savings Program, such as benchmark reports, are difficult to reproduce based on the claims data. However, our goal is to encourage transparency and understanding of these calculations, and we provide webinars and have developed other educational materials to help ACOs better understand the claims data files and other reports. At this time, we do not intend to share the software or source code used to create these reports with the public. However, we will continue to provide user guides, templates, and information packets detailing the metrics and valid data values contained in each of our program reports. These documents are available to ACOs shortly after they are accepted and agree to participate in the Shared Savings Program, and they are available in a user-friendly spreadsheet format. We will continue to work to improve the utility of these reports and will consider these comments as we do so. The quarterly aggregate reports we provide are based on the most recent 12 months of data. The quarterly reports are not calendar year reports; therefore, they do not provide benchmark calculations, which are developed based on the 3 calendar years prior to an ACO's agreement start date.

FINAL ACTION: We are finalizing our policies in § 425.702(c) as proposed. The existing requirements will continue to apply to aggregate reports generated for PY 2015, which will include any quarterly reports or annual reconciliation reports for PY 2015 generated during CY 2016. The new requirements will apply to reports that are generated for PY 2016, including

any PY 2016 reports that are generated in CY 2015 or CY 2017. To ensure the timing of these reports is understood, we have retained the existing rules under § 425.702(c)(1)(i). The rules that apply for PY 2016 and subsequent performance years as finalized have been designated at § 425.702(c)(1)(ii). Specifically, for ACOs in Tracks 1 and 2, we are expanding the list of beneficiaries for which data are made available under § 425.702(c)(1) to include all beneficiaries who had a primary care service visit during the previous 12 months with an ACO participant that submits claims for primary care services that are considered in the assignment process. We are also expanding the beneficiary identifiable information made available for preliminarily prospectively assigned beneficiaries to include additional data points in the following categories: Demographic information, health status information, utilization rates of Medicare services, and expenditures related to utilization of services. We will articulate the data elements associated with the minimum data set in operational guidance and update as needed to reflect changes in the minimum data necessary for ACOs to perform health care operations activities. For Track 3 ACOs, the beneficiary identifiable data included in the reports made available under § 425.702(c) will be limited to the ACO's prospectively assigned beneficiaries.

3. Claims Data Sharing and Beneficiary Opportunity To Decline Claims Data Sharing

a. Overview

Because Medicare FFS beneficiaries have the freedom to choose their health care providers and suppliers, and are not required to receive services from providers and suppliers participating in the ACO, the patients of ACO participants and ACO providers/suppliers often receive care from other providers and suppliers that are not affiliated with the ACO. As a result, ACOs and their ACO participants and ACO providers/suppliers may not be aware of all of the services an assigned beneficiary is receiving. Furthermore, under Tracks 1 and 2, we perform a retrospective reconciliation at the end of each performance year to determine an ACO's assigned beneficiary population based on beneficiaries' use of primary care services using the assignment algorithm described at § 425.402 of the regulations. Therefore, under Tracks 1 and 2, it is often the case that an ACO's preliminary prospective assigned beneficiary list is not complete and does

not include all the beneficiaries who would ultimately be assigned to the ACO at the end of the performance year—that is, all of the beneficiaries for which the ACO ultimately would be held accountable. As we discussed in the April 2011 proposed rule (76 FR 19558) and in the November 2011 final rule (76 FR 67844), we were concerned about ACOs' ability to do their work in the absence of information about services delivered outside of the ACO. We stated our belief at that time that it would be important to give ACOs appropriate access to a beneficiary's identifiable claims data when the beneficiary has received a primary care service billed through the TIN of an ACO participant, and is thus a candidate for assignment at the time of retrospective reconciliation for the performance year. We explained our belief that sharing beneficiary identifiable claims data would enable ACOs to better coordinate and target care strategies towards the individual beneficiaries seen by ACO participants and ACO providers/suppliers.

We ultimately concluded that the bases for disclosure under the HIPAA Privacy Rule were broad enough to cover our disclosure of Medicare Parts A and B claims data to ACOs for health care operations work when certain conditions are met. Similarly, we concluded that the Part D regulations governing the release of Part D data on prescription drug use would permit the release of Part D prescription drug event data to ACOs for purposes of supporting care coordination, quality improvement, and performance measurement activities. Thus, we concluded that we are permitted to disclose the minimum Medicare Parts A, B, and D data necessary to allow ACOs to conduct the health care operations activities that fall into the first or second paragraph of the definition of health care operations under the HIPAA Privacy Rule when such data is requested by the ACO as a covered entity or as the business associate of its covered entity ACO participants and ACO providers/suppliers. Accordingly, in the November 2011 final rule (76 FR 67851), we adopted a policy under which an ACO may request Part A and Part B claims data and Part D prescription drug event data for preliminarily prospectively assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant upon whom assignment is based. In accordance with the terms of the DUA that the ACO must enter into with CMS, data received from CMS under the data sharing provisions of the Shared

Savings Program may only be used for the purposes of clinical treatment, care management and coordination, quality improvement activities, and provider incentive design and implementation. In providing the claims data subject to these limitations, we explained our belief that we would ensure compliance with the requirements of the HIPAA Privacy Rule and the regulations governing the release of Part D data.

While the disclosure of claims data in this manner is within the bounds of the applicable laws, we also noted concerns about beneficiaries' interests in controlling access to their individually identifiable health information. Thus, even though we believed that we had legal authority to make the contemplated disclosures without the consent of beneficiaries, in the November 2011 final rule (76 FR 67849) we implemented the additional requirement at § 425.708 that ACOs offer beneficiaries an opportunity to decline to have their claims data shared with the ACO. We note that in the November 2011 final rule we discussed alternative approaches, such as requiring beneficiary opt-in prior to claims data sharing, however, as stated, we believe that either approach, done well, offers equivalent control for beneficiaries over their personal health information. Moreover, an opt-in would significantly increase paperwork burden. We therefore believe that an opt-out approach is sufficient and appropriate. As such, before requesting access to the beneficiary's data and as part of its broader activities to notify patients that their health care provider or supplier is participating in an ACO, the ACO is required to inform beneficiaries that the ACO may request access to their claims data, and give beneficiaries an opportunity to decline such claims data sharing.

Under the current process for allowing beneficiaries to decline claims data sharing, once the ACO formally requests beneficiary identifiable claims data through the application process, enters into a DUA with CMS, and begins its first performance year, the ACO must supply beneficiaries with a written notification explaining their opportunity to decline claims data sharing. Offering beneficiaries the opportunity to decline claims data sharing may take two forms under current § 425.708. First, if the ACO has formally requested beneficiary identifiable claims data as part of the application process, the ACO must notify each FFS beneficiary of the opportunity to decline claims data sharing when the beneficiary has his or her first visit with an ACO participant

upon whom assignment is based. During this visit, the beneficiary must be provided with written notification informing him or her of the ACO provider/supplier's participation in the ACO and that the ACO may request claims information from CMS in order to better coordinate the beneficiary's care and for other health operations activities. This written notification contains template language created by CMS with the assistance of the Medicare Ombudsman's office and with input from beneficiaries, and explains the beneficiary's option to decline claims data sharing. Once the beneficiary has expressed a preference at the point of care, the ACO may immediately inform CMS of the beneficiary's data sharing preference. If the beneficiary has not declined data sharing, CMS makes that beneficiary's data available to an ACO.

However, we recognized that beneficiaries may not seek primary care services until later in the performance year. Because of this, we offered an alternative option to ACOs who meet the requirements for receiving beneficiary identifiable claims data. Under the alternative option, ACOs may contact beneficiaries via a mailed notification that is sent to all preliminarily prospectively assigned beneficiaries to notify them of their health care provider's participation in an ACO under the Shared Savings Program, and the ACO's intent to request beneficiary identifiable claims data. The mailed notification contains template language that was developed in conjunction with the Medicare Ombudsman's office with input from beneficiaries. If the beneficiary wishes to decline claims data sharing, the beneficiary is instructed to sign the mailed notification and return it to the ACO or call 1-800-Medicare directly. If the ACO chooses to contact beneficiaries via a mailed notification, rather than waiting to notify them at the point of care, the ACO must wait 30 days before submitting the beneficiary's preference and receiving access to the data for those beneficiaries who have chosen not to decline claims data sharing. The 30-day waiting period provides beneficiaries with an opportunity to mail back the notification or to call 1-800-Medicare before the ACO receives access to their claims data. In addition, in order to ensure transparency, beneficiary engagement and meaningful choice, the notification and opportunity to decline claims data sharing must be repeated at the beneficiary's first primary care visit with an ACO participant upon whom assignment is based (76 FR 67850 and

67851). Finally, in addition to the point of care and mailed notifications provided by ACOs, all Medicare FFS beneficiaries are notified through the Medicare & You Handbook about ACOs and the opportunity to decline claims data sharing by contacting CMS directly at 1-800-Medicare.

Once the ACO has notified the beneficiaries according to program rules, and any applicable wait periods are over, the ACO submits the beneficiaries' data sharing preferences to CMS. Beneficiary preferences submitted by ACOs are combined with preferences received by CMS through 1-800-Medicare. Based on these beneficiary preferences, we generate claims files containing the beneficiary identifiable claims data for beneficiaries who have not declined data sharing. These claims files are then made available for ACO access on a monthly basis.

Once a beneficiary has declined data sharing, the beneficiary may choose to reverse the decision by signing another form and sending it to the ACO (which in turn notifies CMS of the beneficiary's updated preference) or by calling 1-800-Medicare directly. We then include the beneficiary's claims data in the claims file provided to the ACO the following month.

In the November 2011 final rule (76 FR 67849), we acknowledged that it is possible that a beneficiary may decline to have his or her claims data shared with an ACO but would choose to continue to receive care from ACO participants and ACO providers/suppliers. In such a case, the ACO would still be responsible for that beneficiary's care, and, as such, although the beneficiary's claims data would not be shared with the ACO, CMS would continue to use the beneficiary's claims data in its assessment of the ACO's quality and financial performance.

In the November 2011 final rule (76 FR 67849 through 67850) we expressed our view that beneficiaries should be notified of their health care provider's participation in an ACO in order to have some control over who has access to their health information for purposes of the Shared Savings Program. We further indicated that the requirement that an ACO provider/supplier engage patients in a discussion about the inherent benefits, as well as the potential risks, of claims data sharing provided an opportunity for true patient-centered care and would create incentives for ACOs, ACO participants, and ACO providers/suppliers to develop positive relationships with each beneficiary under their care. Additionally, we stated

that this policy would provide ACO participants and ACO providers/suppliers the opportunity to engage with beneficiaries by explaining the Shared Savings Program and its potential benefits for both the beneficiaries and the health care system as a whole.

Since implementation of the Shared Savings Program, we have shared claims data on over 7 million beneficiaries with 375 Shared Savings Program ACOs. As we noted in the proposed rule, we have received informal feedback from ACOs that are putting into practice the claims data sharing notification requirements, and from beneficiaries who have received notifications from an ACO that wanted to request access to their claims data. We learned the following from this feedback:

- The option for ACOs to mail notifications and then conduct the in-office follow-up adds to ACOs' financial costs and delays their ability to access claims data in a timely manner. ACOs must wait until January 1 of their first performance year to send out mailings. After waiting the requisite 30 days, the earliest the ACO may submit beneficiary preferences to CMS is in February. The first set of claims data is then available in mid-March. In addition, some ACOs struggle with obtaining current mailing information for preliminarily prospectively assigned beneficiaries, which can delay the mailing of notifications to later in the performance year. Thus, the earliest opportunity for ACOs to receive claims data is mid-February, and that is only the claims data for beneficiaries who visited primary care providers in early January and were given the opportunity to decline claims data sharing at the point of care.

- Stakeholders, including ACOs, ACO participants, and ACO providers/suppliers, continually confuse the notification regarding the ACO's intent to request access to claims data with the separate requirement that all FFS beneficiaries must be notified of ACO participants' and ACO providers/suppliers' participation in the program. Beneficiaries must be notified at the point of care of the ACO participants' and ACO providers/suppliers' participation in an ACO, regardless of whether the ACO has requested or intends to request access to claims data.

- ACOs have commented that beneficiaries are confused about why their providers do not already have access to information regarding other care they may receive, which potentially erodes rather than strengthens the patient-provider relationship. Beneficiaries often assume their

providers have all the information they need to care for them. However, as noted previously, the ACO, its ACO participants, and ACO providers/suppliers would not have claims data for services rendered outside the ACO, and would not necessarily have knowledge about that care.

- Beneficiaries that are preliminarily prospectively or prospectively assigned to an ACO can choose to receive care from any Medicare-enrolled provider or supplier, whether inside or outside the ACO, so beneficiaries may receive notices regarding data sharing from more than one ACO. This is most likely to occur in markets with high ACO penetration where a beneficiary may receive primary care services from several different ACO professionals, each participating in different ACOs. Beneficiaries report confusion, concern, and annoyance over receiving multiple mailings from ACOs, and question why their health care providers do not already have the information they need to appropriately coordinate their care.

- Beneficiaries receiving the notifications giving them the opportunity to decline claims data sharing may mistakenly believe the notification is a request to "opt-out" of ACO care or Medicare FFS, or both, or that they have been placed in a managed care plan without their consent.

- Beneficiaries who receive the letters in the mail notifying them of their provider's participation in an ACO and offering them the opportunity to decline claims data sharing often mistakenly believe that these letters are fraudulent and do not know what to do. Many ACOs are entities that have been newly formed by providers and suppliers for purposes of participating in the Shared Savings Program. While the beneficiary may have a strong relationship with his or her primary care provider, the beneficiary may not recognize the name of the newly formed ACO. Therefore the beneficiary may have concerns and question the legitimacy of the notification.

- Our most recent data indicate that approximately 3 percent of beneficiaries have declined claims data sharing.

As previously discussed, beneficiaries currently have the opportunity to decline claims data sharing by responding to the letters that ACOs send to their preliminarily prospectively assigned beneficiaries, by informing an ACO provider/supplier during a face-to-face primary care service visit, or by contacting 1-800-Medicare directly. We continue to be committed to offering beneficiaries some control over ACO access to their beneficiary identifiable information for purposes of the Shared

Savings Program. However, in light of the feedback we received, we were motivated to review our claims data sharing policies and processes to determine what refinements we could make to mitigate the concerns raised by stakeholders regarding the burden imposed on both beneficiaries and those entities participating in the Shared Savings Program. We considered several aspects of our claims data sharing policies, including the use of various formats to communicate with beneficiaries regarding claims data sharing under the program such as: Mailed notifications to the list of preliminarily prospectively assigned beneficiaries by the ACO; face-to-face discussions with healthcare providers during primary care visits; and CMS' use of 1-800-Medicare and the Medicare & You Handbook. As discussed in the proposed rule, as well as the April 2011 proposed rule (76 FR 19558) and the November 2011 final rule (76 FR 67846), we are convinced by stakeholders that Medicare claims data provide an important supplement to the data to which the ACO and its ACO participants and ACO providers/suppliers already have access. Current law allows CMS to share certain beneficiary identifiable claims data with ACOs when those data are necessary for purposes of certain health care operations. HIPAA does not require that beneficiaries be presented with an opportunity to decline claims data sharing before their PHI can be shared. Moreover, several other CMS initiatives, including the Medicare Health Support demonstration, the Multi-Payer Advanced Primary Care Practice demonstration, the Physician Group Practice demonstration, and the Physician Group Practice Transition demonstration, have successfully shared claims data with providers in the absence of an opportunity for beneficiaries to decline claims data sharing. Therefore, we considered how to retain meaningful beneficiary choice in claims data sharing while reducing the confusion and burden caused by our current claims data sharing policies. As we stated in the proposed rule, we believe meaningful beneficiary choice in claims data sharing is maintained when the purpose and rationale for such claims data sharing are transparent and communicated to beneficiaries, and there is a mechanism in place for beneficiaries to decline claims data sharing. Thus, in revisiting our claims data sharing policies, we sought to maintain claims data sharing transparency and a mechanism for

beneficiaries to decline claims data sharing.

b. Proposed Revisions

Based on our experiences with data sharing under the Shared Savings Program to date, we proposed to modify our processes and policy for claims data sharing while remaining committed to retaining meaningful beneficiary choice over claims data sharing with ACOs. First, we proposed to provide beneficiaries with the opportunity to decline claims data sharing directly through 1-800-Medicare, rather than through the ACO. We noted that 1-800-Medicare has the capability for beneficiaries to use accessible alternative or appropriate assistive technology, if needed. We would continue to maintain a list of beneficiaries who have declined data sharing and ensure that their claims information is not included in the claims files shared with ACOs. Second, we proposed to provide advance notification to all FFS beneficiaries about the opportunity to decline claims data sharing with ACOs participating in the Shared Savings Program through CMS materials such as the Medicare & You Handbook. The Handbook would include information about the purpose of the program, describe the opportunity for ACOs to request beneficiary identifiable claims data for health care operations purposes, and provide instructions on how beneficiaries may decline claims data sharing by contacting CMS directly through 1-800-Medicare. The Handbook would also contain instructions on how a beneficiary may reverse his or her preference to decline claims data sharing by contacting 1-800-Medicare. Third, to reduce burden for both beneficiaries and ACOs, we proposed to remove the option for ACOs to mail notifications to beneficiaries and for beneficiaries to sign and return the forms to the ACO in order to decline claims data sharing. This process would be replaced by a simpler, direct process through notification at the point of care and through 1-800-Medicare as described previously.

We also proposed to continue to require that ACO participants notify beneficiaries in writing at the point of care that their providers and suppliers are participating in the Shared Savings Program as required under § 425.312(a). We proposed that ACO participants would continue to be required to post signs in their facilities using required template language. Rather than requiring ACO participants furnishing primary care services to provide a written form regarding claims data

sharing to all beneficiaries who have a primary care service office visit, we proposed to update the required notification template language for these signs to include information regarding claims data sharing. We would update the template language with the assistance of the Medicare Ombudsman's Office and beneficiary input to inform beneficiaries about both the Shared Savings Program and also that the ACO may request access to beneficiary identifiable claims data from CMS in order to perform health care operations as defined under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. The signs would also provide beneficiaries with information about their opportunity to decline this data sharing and instructions to call 1-800-Medicare if they would prefer that we not share their claims data with an ACO and its ACO participants and ACO providers/suppliers. The signs would likewise include instructions for how beneficiaries may reverse their decision to decline claims data sharing through 1-800-Medicare, if they determine in the future they would prefer to have their claims data made available to ACOs and their ACO participants and ACO providers/suppliers. Because ACO participants are required to post these signs in their facilities at all times, this written notification through the signs would occur at each visit, including the first visit the beneficiary has with an ACO participant during a performance year.

We also noted in the proposed rule that we anticipate that some beneficiaries may continue to want to have the ability to take the information home or into their visit with their primary care provider for further discussion. Therefore, in addition to the signs, we proposed to retain our policy that ACO participants that submit claims for primary care services used to determine the ACO's assigned beneficiary population be required to make a separate written notification form available to the beneficiary upon request. We proposed to modify §§ 425.312 and 425.708 for clarity and to reflect these revised notification policies.

Finally, under Tracks 1 and 2, we proposed to make beneficiary identifiable claims data available in accordance with applicable law on a monthly basis for beneficiaries who are either preliminarily prospectively assigned to the ACO based on the quarterly assignment window or who have received a primary care service from an ACO participant upon whom assignment is based. Because Tracks 1

and 2 use a preliminary prospective assignment methodology with retrospective reconciliation, we stated our belief that ACOs, ACO participants, and ACO providers/suppliers in Tracks 1 and 2 would benefit from access to beneficiary identifiable claims information for all FFS beneficiaries who may be assigned to the ACO at the end of the performance year. In contrast, under Track 3, we proposed to make beneficiary identifiable claims data available only for beneficiaries who are prospectively assigned to an ACO, because the beneficiaries on the prospective assignment list are the only beneficiaries for whom the ACO would be held accountable at the end of the performance year. Consistent with the existing requirements at § 425.704, in order to request beneficiary identifiable claims data, and regardless of track, an ACO must do all of the following:

- Certify that it is a covered entity or the business associate of a covered entity that has provided a primary care service to the beneficiary in the previous 12 months.
 - Enter into a DUA with CMS prior to the receipt of these beneficiary identifiable data.
 - Submit a formal request to receive beneficiary identifiable claims data for such beneficiaries at the time of application to the Shared Savings Program.
 - Certify that the request reflects the minimum data necessary for the ACO to conduct either its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 or health care operations work on behalf of its ACO participants and ACO providers/suppliers that are covered entities (as the business associate of these covered entities) that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.
- We explained our belief that these proposed modifications to our data sharing rules would significantly improve the claims data sharing process. First, we stated our belief that the modified process would reduce burden for beneficiaries who would no longer have to mail back forms. In addition, it would minimize beneficiary confusion in situations where an ACO may be newly formed and may not yet have established a relationship with the beneficiary. Instead, the beneficiary would be able decline claims data sharing, and reverse a decision to decline claims sharing, by contacting CMS directly using 1-800-Medicare. We stated our belief that beneficiaries would be more comfortable expressing

their claims data sharing preferences directly through CMS, an agency with which beneficiaries have an existing relationship. Moreover, we stated our belief that our proposals would streamline ACO operations and would allow ACOs to access beneficiary identifiable claims data earlier in the performance year than is possible under our current policies. Beneficiary identifiable claims data would still be available on a monthly basis, but the new process would be operationally more efficient and less expensive for ACOs. By removing the 30-day delay before ACOs may request beneficiary identifiable claims data for their preliminarily prospectively assigned beneficiaries under Tracks 1 and 2 and prospectively assigned beneficiaries under Track 3, and reducing operational complexities associated with providing these data, ACOs would have access to beneficiary identifiable claims data in a more timely fashion. This could allow ACOs to intervene in the care of beneficiaries earlier during the performance year. In addition, as discussed previously, while we initially believed that requiring ACOs to notify beneficiaries of the opportunity to decline claims data sharing would improve engagement between ACO providers/suppliers that furnish primary care services and their patients, we realized that this policy unintentionally created burden and confusion for both ACOs and beneficiaries, as many beneficiaries assume that their health care providers already have the information needed to optimally coordinate their care, even though this is not always the case. We stated our belief that the proposed revisions to our claims data sharing policy would reduce beneficiary confusion about the Shared Savings Program and the role an ACO plays in assisting the beneficiary's health care providers to improve their health and health care experience, while still retaining a beneficiary's meaningful opportunity to decline claims data sharing.

We also noted in the proposed rule that, since implementation of the program, a small percentage of FFS beneficiaries have requested that their identifiable claims data not be shared and have done so either by notifying the ACO or by contacting 1-800-Medicare to decline claims data sharing. We stated that none of our proposed revisions would have any effect on any existing beneficiary preferences. Previously recorded beneficiary preferences would continue to be honored, unless and until a beneficiary changes his or her preference by

contacting 1-800-Medicare. Accordingly, we noted that our proposal not only would preserve the beneficiary's ability to decline claims data sharing by directly contacting CMS, but it also would have no effect on existing beneficiary claims data sharing preferences, unless the beneficiary subsequently amends his or her preferences to allow claims data sharing.

We noted that the beneficiary identifiable information that is made available under § 425.704 would include Parts A, B and D data, but would exclude any information related to the diagnosis and treatment of alcohol or substance abuse. As we discussed in the April 2011 proposed rule (76 FR 19557), 42 U.S.C. 290dd-2 and the implementing regulations at 42 CFR part 2 restrict the disclosure of patient records by federally conducted or assisted substance abuse programs. Such data may be disclosed only with the prior written consent of the patient, or as otherwise provided in the statute and regulations. We stated that we may revisit this approach as technology in the area of consent management advances.

We sought comment on these proposals, as well as other specific modifications that could be made to our existing policies on data sharing to improve the ability of ACOs to access beneficiary identifiable claims data, and to reduce burden and confusion for ACOs, ACO participants, ACO providers/suppliers, and beneficiaries. We received many comments regarding these proposals.

Comment: Commenters supported our proposal to provide beneficiaries the opportunity to decline claims data sharing directly through 1-800-MEDICARE, rather than through the ACO. Stakeholders commented that the proposed modifications to the claims data sharing process would result in ACOs obtaining claims data sooner; which would allow certain services such as care coordination activities to begin much sooner in the program year. Commenters noted that the modified process would negate the cumbersome process that is currently used by ACOs to track and maintain beneficiary opt out preferences as well as the monthly file transfers of those preferences between the ACO and CMS. A few commenters stated that 1-800-MEDICARE should not be the sole method for a beneficiary to decline data sharing. A commenter suggested developing a Web site that beneficiaries could use to decline claims data sharing electronically.

Response: We appreciate the strong support for our proposals to simplify both the process for beneficiaries to decline claims data sharing and the process for ACOs to notify beneficiaries about this opportunity. We agree with commenters that the modified process will result in the ACO obtaining claims information earlier than is currently possible, which could in turn allow the ACO to intervene in a beneficiary's care earlier in the performance year. However, we do not believe that ACOs should wait for this data before implementing appropriate care coordination and other processes as required under the program rules. We note that defining certain required processes under § 425.112, including processes to coordinate care, and promote evidence-based medicine and patient engagement, and having these processes in place is a requirement for program eligibility. We believe that using 1-800-MEDICARE is an efficient and effective way for beneficiaries to let CMS know directly that they wish to decline claims data sharing because beneficiaries are accustomed to contacting 1-800 Medicare with questions and comments. In addition, 1-800-MEDICARE is staffed with customer service representatives who can answer questions beneficiaries may have about ACOs and claims data sharing. We are finalizing this simplified process for declining claims data sharing and we anticipate it will reduce ACO and beneficiary burden and confusion. Finally, we recognize that although most current beneficiaries are used to contacting 1-800 Medicare with questions and comments, use of the internet and smart phones is becoming ubiquitous, and a new generation of computer-savvy baby-boomers is now becoming eligible for Medicare. Therefore, we will explore whether to establish in the future alternate means by which beneficiaries can elect to decline claims data sharing, such as, for example, through an appropriately secure transaction via the Internet.

Comment: Commenters were supportive of the proposal to notify FFS beneficiaries about the opportunity to decline claims data sharing with ACOs participating in the Shared Savings Program through CMS materials such as the Medicare & You Handbook. Several commenters suggested that CMS take the opportunity to revise and redesign CMS publications to incentivize healthy behaviors and encourage beneficiary engagement with ACOs.

Several commenters stated that CMS should not continue to require ACO participants to provide written notification of their participation in the

Shared Savings Program at the point of care, including notification of the opportunity to decline claims data sharing. However, a few commenters supported the requirement for the ACO and its providers and suppliers to provide written notification at the point of care regarding their participation in the program and the beneficiary's ability to seek care from any FFS provider and the opportunity to decline claims data sharing. A few commenters suggested that CMS require ACOs to develop language for the notifications that would clearly describe why and how the beneficiary's health information would be stored, exchanged, used and protected, along with the beneficiary's opportunity to decline claims data sharing. A commenter suggested that the notification language clearly identify the type of data sharing that would be subject to the opt-out.

A few commenters stated that our proposals should not preclude providers from actively engaging in conversations with beneficiaries regarding the sharing of their claims data and how their claims data will be utilized and stored, or from providing relevant publications regarding beneficiary opt-out opportunities.

Response: We encourage ACOs to work with their ACO participants and ACO providers/suppliers to fully engage their FFS beneficiary population. Also, under the modified beneficiary notification and opportunity to decline data sharing processes, which we are finalizing, we will continue to make available written information for ACO participants to give to beneficiaries at the point of care, which explains what an ACO is and what beneficiaries can expect when their providers are ACO providers/suppliers participating in an ACO. These materials are available to all participating ACOs through the ACO portal.

Additionally, we agree with commenters that ACOs and their participating providers and suppliers should be required at the point of care and in writing to notify beneficiaries of their participation in the program and to provide an opportunity for beneficiaries to decline data sharing. We believe the transparency provided by such notification is important. For this reason, we are also finalizing our proposal that beneficiaries be notified in writing by Medicare regarding the Shared Savings Program and the opportunity to decline claims data sharing in accordance with § 425.708 and by the ACO participant at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program and the opportunity to

decline data sharing in accordance with § 425.312. With respect to the comment about ACOs providing detailed notification about how they handle beneficiary health information, we note that the HIPAA Privacy Rule requires covered entities, including covered health care providers, to provide a notice of privacy practices that describes how they may use and disclose PHI and the individual's rights with respect to PHI. (See 45 CFR 164.520.) Therefore, we believe healthcare providers should already be providing information that describes how beneficiary's health information may be used and disclosed and is protected under the HIPAA Privacy Rule.'

Furthermore, we believe the information contained in the Medicare & You Handbook and the signs posted in ACO participant facilities will prompt beneficiaries to ask questions and engage with their providers concerning their provider's participation in an ACO and the beneficiary's opportunity to decline data sharing. We do not believe these policies will limit or impede a provider's ability or opportunity to engage with beneficiaries at the point of care, and we encourage ACO participants to speak with their beneficiaries about the Shared Savings Program and claims data sharing, including how the ACO uses, stores, and accesses beneficiary data.

Comment: A commenter requested that CMS develop and share with ACOs a list of beneficiaries who have declined to share their claims data, and that CMS analyze this list for the overall impact on the Shared Savings Program.

Response: Currently, for an ACO receiving CCLFs, we provide a monthly file that indicates what beneficiaries have declined data sharing and have held webinars to explore the impact of withheld claims. We intend to continue to provide that information under the new process implemented as a result of this final rule. Additionally, we intend to continue educating ACOs through webinars and other methods regarding the impact of withheld claims.

Comment: Commenters made suggestions related to the type and format of claims data that we share with ACOs, including that CMS:

- Eliminate the suppression of claims data related to alcohol and substance abuse diagnosis and treatment.
- Include a beneficiary demographic file in the monthly claim line feeds.
- Establish a test file process where changes to data sets can be provided in a test file to an ACO in advance of these

changes being incorporated into the live claim feeds.

Response: We noted in the proposed rule that the beneficiary identifiable information that is made available under § 425.704 will include Parts A, B and D data, but will exclude any information related to the diagnosis and treatment of alcohol or substance abuse. As we discussed in the April 2011 proposed rule (76 FR 19557), 42 U.S.C. 290dd-2 and the implementing regulations at 42 CFR part 2 restrict the disclosure of patient records by federally conducted or assisted substance abuse programs. Such data may be disclosed only with the prior written consent of the patient, or as otherwise provided in the statute and regulations. We also noted in the proposed rule, as well as the November 2011 final rule (76 FR 67844), that we expect ACOs will have, or will be working towards having, processes in place to independently identify and produce the data they believe are necessary to best evaluate the health needs of their patient population, including the desired beneficiary demographic data. A robust health information exchange infrastructure and improved communication among ACO participants and the ACO's neighboring health care providers could also result in better access to beneficiary demographic data. We believe the ACO professionals who are providing the plurality of a beneficiary's primary care services have the most up-to-date data. To assist ACOs in identifying the best sources for beneficiary medical record data', we provide the ACO with the TIN and NPI of the ACO participant and ACO professionals that provided the most recent primary care service to the beneficiary on each quarterly report. We also make mock CCLF files available to all ACOs that are eligible to receive claims data. Whenever we make modifications to the CCLF file layouts, we update and supply these mock files to ACOs before we make modifications to the CCLF file layouts.

Comment: Several commenters requested that we make claims data sharing 'automatic' for prospectively assigned beneficiaries and not dependent on an ACO's request for data. Commenters suggested that claims data should be made available for all beneficiaries that are eligible for assignment to an ACO. A commenter requested that CMS provide 3 years of claims data prior to the start of an agreement period rather than the most recent 12-month period at the start of the agreement period.

Response: As we discussed in detail in the December 2014 proposed rule and

the April 2011 proposed rule, we have concluded that we are permitted to disclose the minimum Medicare Parts A, B, and D data necessary to allow ACOs to conduct the health care operations activities that fall into the first or second paragraph of the definition of health care operations under the HIPAA Privacy Rule when such data is requested by the ACO as a covered entity or as the business associate of its covered entity ACO participants and ACO providers/suppliers. Since CMS requires a request to ensure the ACO has met the applicable HIPAA conditions for disclosure, our provision of claims data to ACOs cannot be 'automatic.'

"Consistent with the existing requirements at § 425.704, in order to request beneficiary identifiable claims data, and regardless of track, an ACO must take all of the following steps:

- Certify that it is a covered entity or the business associate of a covered entity that has provided a primary care service to the beneficiary in the previous 12 months.
- Enter into a DUA with CMS prior to the receipt of these beneficiary identifiable data.
- Submit a formal request to receive beneficiary identifiable claims data for such beneficiaries at the time of application to the Shared Savings Program.

- Certify that the request reflects the minimum data necessary for the ACO to conduct either its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 or health care operations work on behalf of its ACO participants and ACO providers/suppliers that are covered entities (as the business associate of these covered entities) that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

Thus, the ACO's formal request to receive data is accomplished at the time of its application to the Shared Savings Program and does not delay the receipt of claims data.

We proposed and are finalizing a policy under Tracks 1 and 2 to make beneficiary identifiable claims data available in accordance with applicable law on a monthly basis for beneficiaries who are either preliminarily prospectively assigned to the ACO or who have received a primary care service from an ACO participant upon whom assignment is based during the most recent 12-month period. Because Tracks 1 and 2 use a preliminary prospective assignment methodology with retrospective reconciliation, we

believe that ACOs, ACO participants, and ACO providers/suppliers in Tracks 1 and 2 will benefit from access to beneficiary identifiable claims information for all FFS beneficiaries who may be assigned to the ACO at the end of the performance year. Furthermore, we believe this policy is consistent with commenters' desire to have access to claims information for a majority of beneficiaries that are eligible to be assigned to the ACO. In contrast, under Track 3, we proposed to make beneficiary identifiable claims data available only for beneficiaries who are prospectively assigned to an ACO, because the beneficiaries on the prospective assignment list are the only beneficiaries for whom the ACO will be held accountable at the end of the performance year.

With respect to the comment about providing 3 years of claims data prior to the start of the agreement period, we continue to believe providing the most recent 12 months of claims data prior to the start of the agreement period is appropriate and sufficient to allow ACOs to coordinate care for their patient population. Our proposals were not intended to revise or extend the "look back" for claims data that we currently provide to ACOs for beneficiaries who have not declined claims data sharing. We also have concerns that expanding the look back period from 12 months prior to the agreement period to 3 years as suggested by the commenter will create barriers for some ACOs because stakeholders have told us that the current CCLF files are large and require sophisticated systems to accept even the 12-months' worth of claims data we provide.

FINAL ACTION: We are finalizing our claims data sharing policies as proposed. Specifically, we are finalizing our proposal in § 425.704 to begin sharing beneficiary identifiable claims data with ACOs participating under Tracks 1 and 2 that request claims data on beneficiaries who are included on their preliminary prospective assigned beneficiary list or that have received a primary care service from an ACO participant upon whom assignment is based during the most recent 12-month period, at the start of the ACO's agreement period, provided all other requirements for claims data sharing under the Shared Savings Program and HIPAA regulations are met. In addition, we are finalizing our proposal to share beneficiary identifiable claims data with ACOs participating under Track 3 that request beneficiary identifiable claims data on beneficiaries who are included on their prospectively assigned beneficiary list. These changes are

effective January 1, 2016 in order to give ACOs in the middle of their 3-year participation agreements some time to make necessary adjustments in light of the new rules. For example, ACOs may need to improve their ability to accept larger amounts of claims data. ACOs will also need some time to finalize the collection and notification to CMS of any beneficiary notifications mailed prior to November 1. The timing will also coincide with a new cohort of ACOs and the issuance of the 2016 Medicare & You Handbook that will notify beneficiaries of the opportunity to decline claims data sharing through 1–800 Medicare. We are finalizing our proposed modifications to § 425.708 to reflect the streamlined process by which beneficiaries may decline claims data sharing. We are finalizing our proposals in § 425.312(a) and § 425.708 to require ACO participants to use CMS-approved template language to notify beneficiaries regarding participation in an ACO and the opportunity to decline data sharing. We are also finalizing our proposal in § 425.708(c) to honor any beneficiary request to decline claims data sharing that is received under § 425.708 until such time as the beneficiary may reverse his or her claims data sharing preference to allow data sharing. These changes are effective November 1, 2015, to enable ACOs that choose to mail notifications under the current requirements to mail notifications to beneficiaries up until the end of October; permit the 30-day window for ACOs to receive notifications from beneficiaries that choose to decline claims data sharing; and give ACOs one last opportunity to notify CMS, in turn, of 'beneficiaries' preferences in December 2015.

E. Assignment of Medicare FFS Beneficiaries

1. Background

Section 1899(c) of the Act requires the Secretary to "determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in paragraph (h)(1)(A)." Section 1899(h)(1)(A) of the Act constitutes one element of the definition of the term "ACO professional." Specifically, this provision establishes that "a physician (as defined in section 1861(r)(1) of the Act)" is an "ACO professional" for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines "physician" as "a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he

performs such function or action". In addition, section 1899(h)(1)(B) of the Act defines "ACO professional" to include practitioners described in section 1842(b)(18)(C)(i) of the Act, such as physician assistants (PAs) and nurse practitioners (NPs).

As we explained in the November 2011 final rule (76 FR 67851), the term "assignment" refers only to an operational process by which Medicare determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from physicians associated with a specific ACO so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care. Consistent with section 1899(b)(2)(A) of the Act, an ACO is held accountable "for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it." The ACO may also qualify to receive a share of any savings that are realized in the care of these assigned beneficiaries due to appropriate efficiencies and quality improvements that the ACO may be able to achieve. The term "assignment" for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care providers and suppliers from whom they receive their services.

In developing the process for assigning Medicare beneficiaries to ACOs, in addition to the definition of an ACO professional (76 FR 67851), we also considered the following elements:

- The operational definition of an ACO (see the discussion of the formal and operational definitions of an ACO in section II.B. of this final rule) so that ACOs can be efficiently identified, distinguished, and associated with the beneficiaries for whom they are providing services.
- The definition of primary care services for purposes of determining the appropriate assignment of beneficiaries.
- Whether to assign beneficiaries to ACOs prospectively, at the beginning of a performance year on the basis of services rendered prior to the performance year, or retrospectively, on the basis of services actually rendered by the ACO during the performance year.
- The proportion of primary care services that is necessary for a beneficiary to receive from an ACO in order to be assigned to that ACO for purposes of this program.

In the November 2011 final rule (76 FR 67851 through 67870), we finalized the methodology that we currently use

to assign beneficiaries to ACOs for purposes of the Shared Savings Program. Beneficiaries are assigned to a participating ACO using the assignment methodology in part 425, subpart E of our regulations. In addition, since the final rule was issued, we have provided additional guidance and more detailed specifications regarding the beneficiary assignment process in operational instructions which are available to the public on the CMS Web site. (<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Financial-and-Assignment-Specifications.html>).

In this section of this final rule, we summarize certain key policies and methodological issues to provide background for several revisions to the assignment methodology that we proposed based on our initial experiences with the program and questions from stakeholders.

2. Basic Criteria for a Beneficiary To Be Assigned to an ACO

As discussed in detail in the proposed rule (79 FR 72791 and 72792) and consistent with previous guidance (see guidance at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Shared-Savings-Losses-Assignment-Spec-v2.pdf>), we proposed to add a new provision at § 425.401(a) of the regulations to outline the criteria that a beneficiary must meet in order to be eligible to be assigned to an ACO. Specifically, we proposed that a beneficiary would be eligible to be assigned to a participating ACO, for a performance year or benchmark year, if the beneficiary meets all of the following criteria during the assignment window (defined in section II.F. of this final rule as the 12-month period used for assignment):

- Has at least 1 month of Part A and Part B enrollment and does not have any months of Part A only or Part B only enrollment.
- Does not have any months of Medicare group (private) health plan enrollment.
- Is not assigned to any other Medicare shared savings initiative.
- Lives in the U.S. or U.S. territories and possessions as determined based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

If a beneficiary meets all of the criteria in § 425.401(a), then the beneficiary would be eligible to be assigned to an ACO in accordance with the two-step beneficiary assignment methodology in § 425.402 and § 425.404. We also

proposed to make a conforming change to § 425.400 to reflect the addition of this new provision. We sought comment on our proposal.

Comment: Commenters generally agreed that the proposed beneficiary eligibility criteria are consistent with the statute, and agreed that their explicit inclusion within the regulations would help to promote a clearer understanding of the assignment process for purposes of such operations as benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment.

Response: We agree that revising the regulations to include these eligibility criteria will help promote understanding of the assignment methodology. We are also make a conforming change to § 425.400 to clarify that the assignment methodology applies for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment.

Comment: A number of commenters suggested additional criteria such as removing the beneficiary if he/she moves from the ACO's service region or otherwise lives in two or more geographic locations during the year. Some commenters requested a policy that geographically defines and pre-identifies the target population for ACOs willing to take financial risk. Commenters suggested such a policy could be defined by distance based on miles, out of state residence, or if one of these geographic factors is combined with attribution, on a limited number of attributing services billed over a short period of time. To illustrate, some commenters suggested that to be eligible for ACO assignment, beneficiaries should receive a large majority (for example, 75 to 95 percent) of their qualified primary care services delivered in the ACO's service area. Another commenter suggested that CMS implement a beneficiary assignment appeals process to allow for removal of beneficiaries from assignment to an ACO if they meet certain conditions such as move out of the area or select a new non-ACO physician. These commenters believe that ACOs should not be financially accountable for patients who live outside of their service area, such as those who move during the year or otherwise live in two or more geographic locations during the year. In such cases, commenters noted that it may be difficult for the ACO to which the patient is assigned to manage effectively the beneficiary's care throughout the year. In addition, that

ACO will be held accountable for the cost and quality of the care provided to the beneficiary in the alternate location, which may have different standards of practice. A few commenters requested that beneficiaries who opt out of sharing their data should also not be assigned to an ACO.

Response: We greatly appreciate the varied suggestions for additional criteria for excluding beneficiaries from assignment. We explored some of these suggestions and performed an initial analysis on the specific suggestion for removal of beneficiaries who move out of the ACO's service area and determined there is a very small number of beneficiaries who will meet the criteria for exclusion on this basis, and these beneficiaries will not represent a significant portion of the ACO's list. We further point out that for Tracks 1 and 2, beneficiaries who move may drop off an ACO's assignment list since the lists are retrospectively reconciled. Under Tracks 1 and 2, a beneficiary only gets retrospectively assigned to an ACO if he/she received a plurality of primary care services from ACO professionals at the ACO. Therefore, we believe the ACO can reasonably be held accountable for the overall cost and quality of the care furnished to that beneficiary during that performance year. This policy has an additional advantage of providing an incentive for ACOs to coordinate care and provide for an appropriate hand-off when beneficiaries move out of their service area. Likewise, we believe that continuing to include those beneficiaries who have not permanently moved, but who otherwise live in two or more geographic locations during the year, on the ACO's assignment list during the performance year provides an excellent opportunity for ACOs to make sure the care for such beneficiaries is coordinated. Finally, regarding the suggestion that beneficiaries who opt out of sharing their data should not be assigned to an ACO, we believe the assignment methodology adequately indicates which beneficiaries should be assigned to an ACO on the basis of the primary care services furnished by ACO professionals. In addition, ACOs will have their own clinical information about the patient that they may share and use as permitted by HIPAA and other applicable laws. Therefore, we believe the beneficiary should remain assigned to the ACO even if the beneficiary does not choose to permit us to disclose his/her PHI in the form of claims data. We intend to monitor and assess the impact of not excluding these beneficiaries from assignment and, if

appropriate, may consider making adjustments in future rulemaking.

Comment: A commenter suggested exclusion of Medicare beneficiaries who are already deceased at the time of their initial assignment to an ACO. The commenter stated that ACOs are prevented from coordinating the care of these beneficiaries and from learning from their claims experience. The commenter noted that this is a critical issue because many studies have shown that Medicare beneficiaries spend a disproportionate share of their lifetime medical expenses in the last few months of life. The commenter believes that assigning such beneficiaries to an ACO is an unfair burden on their financial performance under the Shared Savings Program and their fair opportunity to earn shared savings.

Response: We appreciate this comment. However, we are not revising the program's assignment methodology to remove beneficiaries with a date of death during the assignment window. Including beneficiaries with a date of death during the assignment window helps to reduce the introduction of actuarial bias when comparing the ACO's benchmark and performance year expenditures. Beneficiaries who are deceased will only be assigned to an ACO under either a prospective or retrospective assignment methodology if the ACO had previously been treating the beneficiary and providing the beneficiary's plurality of primary care services. Further, a purpose of sharing the preliminary list of assigned beneficiaries is to give the ACO information about their Medicare FFS patient population. On the reports we give to ACOs, we indicate if a beneficiary is deceased. The ACO can learn about the beneficiary's experience by seeking information from both the ACO providers/suppliers as well as any of the beneficiary's other Medicare-enrolled providers and suppliers that cared for the beneficiary during the assignment window to the extent permitted by HIPAA and other applicable laws, and by reviewing the monthly beneficiary-identifiable claims line feeds (if the ACO properly requested these data). We believe it is better to include deceased beneficiaries for the sake of completeness. Further, we do not believe it is unfair to the ACO because such beneficiaries are represented in both benchmark and performance years. Accordingly, we believe it is appropriate that ACOs be held accountable for beneficiaries who pass away during a performance year.

Comment: A few commenters suggested that the criterion that a beneficiary not have any months of

Medicare group (private) health plan enrollment during the assignment window be revised to not more than 3 to 6 months, to account for certain situations where beneficiaries, such as dual eligible, might change, enroll in or disenroll from plans more frequently. This would allow such beneficiaries to remain attributed to the ACO.

Response: Section 1899(c) of the Act requires the Secretary to "determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO". As required by section 1899(c) of the Act, and consistent with the definition of Medicare FFS beneficiary in section 1899(h)(3) of the Act § 425.20 of the regulations, only beneficiaries enrolled in traditional Medicare FFS under Parts A and B are eligible to be assigned to an ACO participating in the Shared Savings Program. We believe our current policy is consistent with these requirements because under our current approach, only beneficiaries enrolled in traditional Medicare FFS under Parts A and B throughout the full performance year are eligible to be assigned to an ACO, and therefore, we will not revise the policy at this time. However, we plan to consider this issue further and we may address this issue in future rulemaking.

FINAL ACTION: We are finalizing our proposal to codify the criteria that a beneficiary must meet in order to be eligible to be assigned to an ACO. Specifically, a beneficiary will be eligible to be assigned to an ACO, for a performance year or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

- Has at least 1 month of Part A and Part B enrollment and does not have any months of Part A only or Part B only enrollment.
- Does not have any months of Medicare group (private) health plan enrollment.
- Is not assigned to any other Medicare shared savings initiative.
- Lives in the U.S. or U.S. territories and possessions as determined based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

We are also finalizing our proposal to add a new provision at § 425.401(a) of the regulations outlining these criteria. If a beneficiary meets all of the criteria in § 425.401(a), then the beneficiary will be eligible to be assigned to an ACO in accordance with the two-step beneficiary assignment methodology in § 425.402 and § 425.404. We also are finalizing the conforming change to § 425.400 to reflect the addition of this new provision and additional

conforming changes to § 425.400 to clarify that these revisions apply for purposes of benchmarking, preliminary prospective assignment (including quarterly updates which are in turn used to determine a sample of beneficiaries for purposes of assessing the ACO's quality performance), retrospective reconciliation, and prospective assignment.

3. Definition of Primary Care Services

a. Overview

As discussed in the proposed rule (79 FR 72792), we currently define "primary care services" for purposes of the Shared Savings Program in § 425.20 as the set of services identified by the following HCPCS/CPT codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439). In addition, as we will discuss later in this section, we have established a crosswalk for these codes to certain revenue center codes used by FQHCs (prior to January 1, 2011) and RHCs so that their services can be included in the beneficiary assignment process.

As we explained in the proposed rule (79 FR 72792), we established the current list of codes that constitute primary care services because of our belief that the listed codes represented a reasonable approximation of the kinds of services that are described by the statutory language at section 1899(c) of the Act, which refers to assignment of "Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services" furnished by physicians. In addition, we selected this list to be largely consistent with the definition of "primary care services" in section 5501 of the Affordable Care Act, which establishes the Primary Care Incentive Payment Program (PCIP). The PCIP was established to expand access to primary care services, and thus its definition of "primary care services" provides a compelling precedent for adopting a similar list of codes for purposes of the beneficiary assignment process under the Shared Savings Program. We slightly expanded the list of codes found in section 5501 of the Affordable Care Act to include the Welcome to Medicare visit (HCPCS code G0402) and the annual wellness visits (HCPCS codes G0438 and G0439) as primary care services since these codes clearly represent primary care services frequently received by Medicare beneficiaries, and in the absence of the special G codes the services provided during these visits would be described by one or more of the regular office visit

codes that are included in the list under section 5501 of the Affordable Care Act.

b. Proposed Revisions

As discussed in detail in the proposed rule (79 FR 72792 through 72794), we proposed to update the definition of primary care services at § 425.20 to include the transitional care management (TCM) codes (CPT codes 99495 and 99496) and the chronic care management (CCM) code HCPCS code GXXX1, which was replaced by CPT 99490 in the 2015 Medicare Physician Fee Schedule final rule. (See discussion at 79 FR 67716). We also proposed to include these codes in our beneficiary assignment methodology under § 425.402.

Specifically, effective January 1, 2013, Medicare pays for two CPT codes (99495 and 99496) that are used to report physician or qualifying non-physician practitioner TCM services for a patient following a patient's discharge to a community setting from an inpatient hospital or skilled nursing facility (SNF) or from outpatient observation status in a hospital or partial hospitalization. These codes were established to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or SNF stay.

In addition, effective January 1, 2015, Medicare pays for CCM services (see 79 FR 67715 through 67728). CCM services generally include regular development and revision of a plan of care, communication with other treating health professionals, and medication management.

Further, in order to promote flexibility for the Shared Savings Program and to allow the definition of primary care services used in the Shared Savings Program to respond more quickly to HCPCS/CPT coding changes made in the annual PFS rulemaking process, we proposed to make any future revisions to the definition of primary care service codes through the annual PFS rulemaking process. Accordingly, we also proposed to amend the definition of primary care services at § 425.20 to include additional codes that we designated as primary care services for purposes of the Shared Savings Program, including new HCPCS/CPT codes or revenue codes and any subsequently modified or replacement codes. We sought comments on these proposals.

As discussed in detail in the proposed rule (79 FR 72792 through 72793), we also welcomed comment from stakeholders on the implications of retaining certain evaluation and management (E&M) codes used for

physician services furnished in SNFs and other nursing facility settings (CPT codes 99304 through 99318) in the definition of primary care services. As we noted in the proposed rule, in some cases, hospitalists that perform E&M services in SNFs have requested that these codes be dropped from the definition of primary care services so that their ACO participant TIN need not be exclusive to only one ACO based on the exclusivity policy established in the November 2011 final rule (76 FR 67810 through 67811). The requirement under § 425.306(b) that an ACO participant TIN be exclusive to a single ACO applies when the ACO participant TIN submits claims for primary care services that are considered in the assignment process. However, ACO participant TINs upon which beneficiary assignment is not dependent (that is, ACO participant TINs that do not submit claims for primary care services that are considered in the assignment process) are not required to be exclusive to a single ACO. We indicated in the proposed rule that we continued to believe that it is reasonable to conclude that services provided in SNFs with CPT codes 99304 through 99318 represent basic E&M services that would ordinarily be provided in physician offices if the beneficiaries were not residing in nursing homes and should continue to be included in the definition of primary care services used for purposes of beneficiary assignment to an ACO participating in the Shared Savings Program.

Finally, we sought comments as to whether there are any additional existing HCPCS/CPT codes that we should consider adding to the definition of primary care services in future rulemaking for purposes of assignment of beneficiaries to ACOs under the Shared Savings Program.

Comment: Almost all commenters supported the proposal to include TCM and CCM in the definition of primary care, agreeing that the care coordination and care management services included under these codes are consistent with the delivery of primary care and will assist ACOs in lessening fragmentation and improving care coordination. A very small number of commenters opposed including these codes, suggesting that because they are new codes still untested in the market place, there could be unintended consequences, such as that there could be a propensity to double-pay for these services if attribution rules are not written properly since the possibility exists that beneficiaries may be seeing multiple providers in different locations. A commenter suggested there

should be a minimum of 1 year experience under the new codes available before they are used for assignment in the performance year. Another commenter believes that inclusion of CCM should be delayed until other concerns are addressed. For example, this commenter suggested that an ACO should be permitted to control utilization of CCM for its assigned beneficiaries, allowing an ACO to bill for CCM directly (assuming that all the requirements for billing the CCM code are met by the ACO) and superseding claims submitted by ACO providers/suppliers. A commenter pointed out that in the 2015 Medicare Physician Fee Schedule final rule, CMS opted to use CPT code 99490 for the CCM services instead of HCPCS code GXXX1.

Response: For the reasons discussed in the proposed rule, we agree with commenters who believe that the care coordination and care management services included under these codes are consistent with the delivery of primary care and will assist ACOs in lessening fragmentation and improving care coordination. We agree that we should use CPT code 99490 for the Chronic Care Management (CCM) services instead of HCPCS code GXXX1. (See the discussion at 79 FR 67716). We do not believe it is necessary to allow for a transition period for ACOs and their ACO participants to gain experience with these codes before incorporating them into the assignment process. We believe the coding definitions and other criteria that have been developed by CPT and CMS will facilitate use of these codes by ACO participants. Further, we do not believe it is appropriate for ACOs to use these or any other codes as a way to control utilization by the ACO participants.

Comment: A commenter recommended that emergency department visits count as primary care visits for purposes of assignment and that ACO participants should be encouraged to modify delivery of care in the ED to provide 24-hour access to care, but with a redesigned payment and delivery system that promotes primary care, meets the needs of rural communities and keeps costs down. Another commenter requested inclusion of inpatient E&M codes: Observation—99218–99220/Initial, 99224–99226/Subsequent; Hospital Inpatient—99221–99223/Initial, 99231–99233/Subsequent; and Hospital Inpatient Consultation—99251–99255.

Response: For the reasons we discussed in the initial Shared Savings Program final rule (76 FR 67853), we continue to believe that the services represented by these codes do not

represent the kind of general evaluation and management of a patient that will constitute primary care. In addition, we will also note that these codes were not included in the definition of “primary care services” in section 5501 of the Affordable Care Act. That section establishes an incentive program to expand access to primary care services, and thus the definition of “primary care services” under that program provides a compelling reason for adopting a similar definition and list of codes for purposes of the Shared Savings Program.

Comment: A commenter requested clarification of how CMS would be modifying the ETA processes to reflect a change in coding policy under the Outpatient Hospital Prospective Payment System (OPPS) effective for services furnished on or after January 1, 2014.

Response: Effective January 1, 2014, CPT codes 99201 through 99205 and 99211 through 99215 are no longer recognized for payment under the OPPS. Under the OPPS, outpatient hospitals have been instructed to use HCPCS code G0493 and may no longer use 99201 through 99205 and 99211 through 99215. (For example, see our Web site at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8572.pdf>, page 3). This coding change under OPPS affects our ETA operational processes under the Shared Savings Program. This new information about how clinic visits are billed under OPPS came to light after the issuance of the December 2014 proposed rule. Therefore, we need to reconsider our ETA hospital-related proposal and intend to address the issue in future rulemaking. We discuss the primary care codes we use for ETA hospitals in section II.E.5. of this final rule.

Comment: Some commenters—in response to the discussion in the proposed rule regarding including the codes for SNF visits, CPT codes 99304 through 99318 in the definition of primary care services—objected to inclusion of SNF visit codes because they believe a SNF is more of an extension of the inpatient setting rather than a component of the community based primary care setting. These commenters believe that ACOs are often inappropriately assigned patients who’ve had long SNF stays but would not otherwise be aligned to the ACO and with whom the ACO has no clinical contact after their SNF stay. Some commenters draw a distinction between the services represented by these codes when provided in two different places of service, POS 31 (SNF) and POS 32

(NF). While the same CPT visit codes are used to describe these services in SNFs (POS 31) and NFs (POS 32), the patient population is arguably quite different. These commenters suggest excluding SNF visit codes furnished in POS 31 to relieve ACO participants that bill for the services of hospitalists from the requirement that they must be exclusive to a single ACO if their services are considered in assignment. Patients in SNFs (POS 31) are shorter stay patients who are receiving continued acute medical care and rehabilitative services. While their care may be coordinated during their time in the SNF, they are then transitioned back to the community. Patients in a SNF (POS 31) require more frequent practitioner visits—often from 1 to 3 times a week. In contrast, patients in NFs (POS 32) are almost always permanent residents and generally receive their primary care services in the facility for the duration of their life. Patients in NFs (POS 32) are usually seen every 30 to 60 days unless medical necessity dictates otherwise. Another commenter suggested that we should consider establishing separate CPT codes to distinguish between E&M services provided by SNFs vs other nursing facilities.

Response: We appreciate receiving these suggestions on how we could create a method to exclude services billed for beneficiaries receiving Part A SNF care from the definition of “primary care services” by using POS 31 to identify such claims. We plan to consider this issue further and will discuss it in future rulemaking.

Comment: A commenter requested that we establish a separate definition for “beneficiary assignment services” that will reflect the primary care services used to assign beneficiaries to ACOs under § 425.20. In this way, CMS could satisfy the need to narrowly define ACO assignment while continuing to broaden the definition of “primary care” in a manner consistent with a wide range of CMS’ health reform efforts.

Response: We do not believe that this revision is necessary. The definition of primary care services under § 425.20 applies only to the Shared Savings Program and does not directly affect other CMS programs.

Comment: A few commenters supported CMS’s proposal to make any future revisions to the definition of primary care service codes through the annual PFS rulemaking process.

Response: We believe such a process will provide CMS with flexibility to address any future appropriate revisions to the definition of primary care service

codes promptly. ACOs and other interested stakeholders will continue to have an opportunity as part of the annual PFS rulemaking to provide input before any revisions to the definition of primary care services are implemented.

FINAL ACTION: We are finalizing our proposal to update the definition of primary care services at § 425.20 to include both TCM codes (CPT codes 99495 and 99496), the CCM code (CPT code 99490), and to include these codes in our beneficiary assignment methodology under § 425.402. Further, we are finalizing our proposal to amend § 425.20 to make any future revisions to the definition of primary care service codes through the annual PFS rulemaking process.

4. Consideration of Physician Specialties and Non-Physician Practitioners in the Assignment Process

a. Overview

Primary care services can generally be defined based on the type of service provided, the type of provider specialty that provides the service, or both. As discussed in detail in the proposed rule (79 FR 72794) our current assignment process simultaneously maintains the requirement to focus on primary care services in beneficiary assignment, while recognizing the necessary and appropriate role of specialists in providing primary care services, such as in areas with primary care physician shortages.

Under § 425.402, after identifying all patients who had a primary care service with a physician who is an ACO professional (and who are thus eligible for assignment to the ACO under the statutory requirement to base assignment on “utilization of primary care services” furnished by physicians), we employ a step-wise assignment process that occurs in the following two steps:

Step 1: In this step, first we add up the allowed charges for primary care services billed by primary care physicians through the TINs of ACO participants in the ACO. Next, we add up the allowed charges for primary care services furnished by primary care physicians that are billed through other Medicare-enrolled TINs (or through a collection of ACO participant TINs in the case of another ACO). If the allowed charges for the services furnished by ACO participants are greater than the allowed charges for services furnished by the participants in any other ACO or by any non-ACO participating Medicare-enrolled TIN, then the beneficiary is assigned to the ACO in the first step of the assignment process.

Step 2: This step applies only for beneficiaries who have not received any primary care services from a primary care physician. We assign a beneficiary to an ACO in this step if the beneficiary received at least one primary care service from a physician participating in the ACO, and more primary care services (measured by Medicare allowed charges) from ACO professionals (physician regardless of specialty, NP, PA or clinical nurse specialist (CNS)) at the ACO than from ACO professionals in any other ACO or solo practice/group of practitioners identified by a Medicare-enrolled TIN or other unique identifier, as appropriate, that is unaffiliated with any ACO.

Since publication of the November 2011 final rule (76 FR 67853 through 67858), we have gained further experience with this assignment methodology. We have learned from its application for the first 400 ACOs participating in the program that, for the total 7.1 million assigned beneficiaries, about 92 percent of the beneficiaries assigned to ACOs are assigned in step 1, with only about 8 percent of the beneficiaries being assigned in step 2. We have adopted a similar beneficiary assignment approach for some other programs, such as the PQRS Group Practice Reporting Option via the GPRO web interface (77 FR 69195 through 69196) and the Value Modifier (VM) (79 FR 67790 and 79 FR 67962).

We continue to believe that the current step-wise assignment methodology generally provides a balance between maintaining a strong emphasis on primary care while ultimately allowing for assignment of beneficiaries on the basis of how they actually receive their primary care services. However, we proposed several revisions that we believe would improve the assignment methodology.

b. Proposed Revisions

(1) Including Primary Care Services Furnished by Non-Physician Practitioners in Step 1

First, we proposed to include primary care services furnished by non-physician practitioners (NPs, PAs, and CNSs) in step 1 of the assignment methodology rather than only in step 2 as they are under the current process. We discussed the reasons for this proposal in detail in the proposed rule (79 FR 72795). In summary, including services furnished by NPs, PAs, and CNSs in determining the plurality of primary care services in step 1 of the assignment process may help ensure that beneficiaries are assigned to the ACO (or non-ACO entity) that is

actually providing the plurality of primary care for that beneficiary and thus, should be responsible for managing the patient’s overall care. We also noted that section 5501 of the Affordable Care Act defines a “primary care practitioner” as a physician who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine or as a “nurse practitioner, clinical nurse specialist, or physician assistant.” Therefore, we believe that it would be appropriate to include these non-physician practitioners in step 1 of the assignment process in order to better align the Shared Savings Program assignment methodology with the primary care emphasis in other provisions of the Affordable Care Act. Further, we believe that including these non-physician practitioners in step 1 would be supported by the statute as long as we continue to first identify all patients that have received a primary care service from a physician who is an ACO professional and who are thus eligible for assignment to the ACO under the statutory requirement to base assignment on “utilization of primary care services” furnished by physicians. Accordingly, we proposed to amend the assignment methodology to include primary care services furnished by NPs, PAs, and CNSs in step 1 of the assignment process. Specifically, we proposed to revise § 425.402(a) to include NPs, PAs, and CNSs as ACO professionals that would be considered in step 1 of the assignment process. We sought comments on our proposal.

However, we also noted that there could be some concerns about adding NPs, PAs, and CNSs to step 1 of the assignment methodology. Unlike for physicians, the CMS self-reported specialty codes reported on claims for NPs, PAs, and CNSs are not further broken down by specific specialty areas. Therefore, the codes do not allow practitioners to indicate whether they are typically functioning as primary care providers or as specialists. We expressed concern that by considering services furnished by NPs, PAs, and CNSs in step 1, we may ultimately assign some beneficiaries to an ACO inappropriately based on specialty care over true primary care. Thus, while we invited comments on our proposal to include primary care services furnished by NPs, PAs, and CNSs in step 1 of the assignment methodology, we also requested comment on the extent to which these non-physician practitioners provide non-primary care services and whether there are ways to distinguish between primary care services and non-

primary care services billed by these non-physician practitioners.

Comment: Most commenters supported this proposal, at least in concept, agreeing that many NPs, PAs, and CNSs are engaged in the delivery of primary care and their inclusion within Step 1 can provide for a more accurate primary care-based assignment. However, many of these commenters also pointed out that some NPs, PAs, and CNSs furnish specialty care and not primary care. Therefore, these commenters suggested that CMS should take additional steps to assure that the NPs, PAs, and CNSs considered under Step 1 are truly primary care providers in order to better assure accurate assignment of beneficiaries to ACOs. These commenters provided a wide range of suggestions. These suggestions included developing new, more detailed specialty codes for NPs, PAs, and CNSs; implementing a primary care attestation process for non-physician practitioners that would be somewhat similar to the attestation process that is currently used for physicians that furnish primary care services in FQHCs/RHCs; implementing such a primary care attestation process for all ACO professionals including both physicians and non-physician practitioners; revising the CMS PECOS enrollment system to require non-physician practitioners to indicate whether they provide primary care; analyzing claims data to determine whether a relationship exists between a non-physician practitioner and a primary care physician; using service code modifiers to clearly identify the clinician performing a specific service; and giving each ACO the option to include or not include non-physician practitioners for their beneficiary assignments, among other suggestions.

Some commenters supporting the proposal acknowledged that NPs are not classified in specialty codes by CMS, but believe this is unlikely to be a serious problem. For example, a commenter indicated that recent surveys found that, of the 205,000 NPs in the U.S., more than 87 percent are prepared in primary care and more than 75 percent practice in at least one primary care site. Another commenter stated that NPs are prepared and certified in the primary care specialties with basically the same frameworks as physicians: Family, adult (internal medicine) and gerontology, and that women's health NPs are focused on primary care. Another commenter noted that there exists the same inability to discern whether physicians are actually providing primary care services versus non-primary care services. These commenters requested that CMS not

create barriers for one group of ACO professionals with requirements that are not placed on others.

A few commenters opposed including non-physician practitioners in step 1 because Medicare claims data is not able to distinguish between their primary care and specialty care. A commenter opposed assigning a beneficiary to an ACO based solely on services delivered by a non-physician ACO professional.

Response: We agree with commenters who believe including NPs, PAs, and CNSs in step 1 of the assignment methodology will further strengthen our current assignment process. Including services furnished by NPs, PAs, and CNSs in determining the plurality of primary care services in step 1 of the assignment process may help ensure that beneficiaries are assigned to the ACO (or non-ACO entity) that is actually providing the plurality of primary care for that beneficiary and thus, should be responsible for managing the patient's overall care. In this way, all primary care services furnished by the entire primary care physician and practitioner team (including NPs, PAs, and CNSs working in clinical teams in collaboration with or under the supervision of physicians), will be considered for purposes of determining where a beneficiary received the plurality of primary care services under step 1 of the assignment methodology.

At this time, we will not establish special procedures to determine whether NPs, PAs, and CNSs are actually performing primary care and not specialty care. We agree with commenters who indicated that most non-physician practitioners have been prepared in primary care or provide services in primary care settings or both, and that we should not unnecessarily create barriers for one group of ACO professionals with requirements that are not placed on others. Furthermore, we note that any non-physician practitioner services furnished and billed as "incident to" the services of a specialist physician will be billed under the specialist physician's NPI. Therefore, such "incident to" non-physician services will be excluded from Step 1 of the assignment process. However, we will continue to monitor this issue.

Also we further clarify that beneficiaries will not be assigned to ACOs solely based on services provided by non-physician practitioners. We will continue under § 425.402 to first identify all patients who have received a primary care service from a physician who is an ACO professional and who are thus eligible for assignment to the ACO under the statutory requirement to

base assignment on "utilization of primary care services" furnished by physicians.

Comment: A commenter believes that CMS should allow primary care physicians to identify collaborating allied professionals, such as NPs, to act "on their behalf," so those visits would not count against them in the attribution process. The commenter stated that this should be allowed even if the collaborating allied professional is under an entity with a different Medicare-enrolled TIN.

Response: We disagree. Primary care services furnished by physicians and non-physicians are all included in the assignment algorithm if they are billed under the TIN of an ACO participant. We do not believe it would be appropriate under the beneficiary assignment process to include such primary care services billed under a TIN that has not agreed to participate in the ACO.

Comment: A commenter encouraged CMS to assign Medicare beneficiaries directly to ACOs on the basis of primary care services provided by NPs and PAs, only when such services are provided in a manner consistent with state law requirements, including requirements related to physician supervision.

Response: We do not believe it is necessary to establish such additional criteria for the Shared Savings Program. Primary care services provided by NPs and PAs are only payable under the PFS when such services are provided in a manner consistent with state law requirements, including requirements related to physician supervision.

FINAL ACTION: We are finalizing our proposal to amend § 425.402(a) to include claims for primary care services furnished by NPs, PAs, and CNSs under step 1 of the assignment process, after having identified beneficiaries who received at least one primary care service by a physician participating in the ACO. The current methodology will continue to be used for PY 2015, including reconciliation, while the new methodology will be used for operations related to PY 2016. Thus, we are retaining the rules for the current methodology under § 425.402(a) and the methodology that will be applicable for performance years beginning in 2016 has been designated under § 425.402(b).

(2) Excluding Services Provided by Certain Physician Specialties From Step 2

Second, we proposed to exclude services provided by certain physician specialties from step 2 of the assignment process. We made this proposal partly to address stakeholder concerns that by

including such claims in step 2 of the assignment process, the ACO participant TINs that submit claims for services furnished by certain specialists are limited to participating in only one ACO because of the exclusivity requirement under § 425.306(b) of the regulations. This requirement is discussed in the November 2011 final rule (76 FR 67810 through 67811). Specifically, some stakeholders have stated that certain specialties that bill for some of the E&M services designated as primary care services under § 425.20 do not actually perform primary care services. We agree that although some specialties such as surgeons and certain others bill Medicare for some of the Shared Savings Program “primary care” codes, in actual practice the services such specialists perform when reporting these codes do not typically represent primary care services because the definitions of HCPCS/CPT codes for office visits and most other E&M services are not based on whether primary care is provided as part of the service. Accordingly, we agree that to identify primary care service claims more accurately, the CPT codes for primary care services should be paired with the specialties of the practitioners who render those services and that it would be appropriate to exclude claims for services provided by certain physician specialties from the beneficiary assignment process.

Therefore, we proposed to exclude services provided by certain CMS physician specialties from the beneficiary assignment process. The net effect of this proposal would be to exclude certain claims from determining the ACO’s assigned population. The proposed lists of physician specialties that would be included in and excluded from the assignment process (provided in Tables 1 through 4 of the proposed rule and also included in Tables 2 through 5 in this final rule) were based on recommendations by CMS medical officers knowledgeable about the services typically performed by physicians and non-physician practitioners. However, we note that given the many requests and comments from specialists and specialty societies asking to have their services included in the assignment methodology that we received during the original rulemaking to establish the Shared Savings Program, in the proposed rule we attempted to limit the list of physician specialty types that would be excluded from the assignment process to those physician specialties that would very rarely, if ever, provide primary care to beneficiaries. As a general rule, for

example, we expected that physicians with an internal medicine subspecialty such as nephrology, oncology, rheumatology, endocrinology, pulmonology, and cardiology would frequently provide primary care to their patients. Especially for beneficiaries with certain chronic conditions (for example, certain heart conditions, cancer or diabetes) but who are otherwise healthy, we expect that these specialist physicians often take the role of primary care physicians in the overall treatment of the beneficiaries if there is no family practitioner or other primary care physician serving in that role. In contrast, we expect that most surgeons, radiologists, and some other types of specialists would not typically provide a significant amount of primary care, if any, and therefore we proposed to exclude their services from the assignment process.

We proposed to amend § 425.402 by adding a new paragraph (b) to identify the physician specialty designations that would be considered in step 2 of the assignment process. We also proposed to modify the exclusivity requirement at § 425.306(b) to clarify how the exclusivity rules would be affected by this proposal to exclude certain specialists from step 2 of the assignment methodology. Specifically, we proposed to revise § 425.306(b) to indicate that each ACO participant who submits claims for primary care services used to determine the ACO’s assigned population must be exclusive to one Shared Savings Program ACO.

In addition, we proposed to make several conforming and technical changes to § 425.402(a). First, we proposed a modification to provide that for purposes of determining whether a beneficiary has received a primary care service from a physician who is an ACO professional, we would consider only services furnished by primary care physicians or physicians with a specialty listed in new paragraph (b). Secondly, we proposed to make modifications to conform with changes in the definitions of “assignment,” “ACO professional,” and “ACO provider/supplier” in addition to our proposal to adopt a prospective assignment approach under proposed Track 3, which is discussed in section II.F. of this final rule. We sought comment on these proposals. We received a high volume of comments on this proposal.

Comment: Commenters agreed with the proposal to remove from the assignment process those claims submitted by physician specialties (for example, surgeons) that, despite using the general purpose CPT and HCPCS

codes defined as “primary care” under current regulations, do not actually perform primary care services. Some commenters suggested specialty specific revisions to CMS’ proposal. However, in a few cases commenters were not in agreement about whether specific specialties should be included in step 2 or not. For example, a few commenters supported including physical medicine and rehabilitation, rheumatology, and OB/GYN whereas a few other commenters requested they be removed. A number of commenters suggested we modify our proposals based on input from each individual specialty organization. Other commenters requested revisions to CMS’ proposals regarding specialties to be included in step 2 of the beneficiary assignment process are as follows:

A commenter urged CMS to include pediatric medicine (specialty code 37) as an explicit part of the beneficiary assignment step 1 rather than step 2. The commenter noted that many elements of the framework that CMS constructs for Medicare ACOs will guide future proposals for Medicaid ACOs, as well as the design of similar plans by commercial payers or large self-insured groups.

Commenters requested that psychiatrists (specialty codes 26, 27, 79, and 86) be included in step 2 assignment. These commenters indicated psychiatry is frequently the point of first contact for persons with undiagnosed conditions and that there are a number of important reasons why most persons with serious mental illness would rather receive their care from their psychiatrist rather than primary care physicians.

Other commenters requested that CMS include specialty code 12 (osteopathic manipulative medicine) in step 2 because osteopaths frequently provide primary care services. These commenters also requested that CMS update this specialty code name in Table 4 of this final rule.

A commenter urged CMS to exclude hospice and palliative medicine (specialty code 17) from step 2 of the beneficiary assignment process in the final rule. The commenter that while many hospice and palliative care physicians have formal relationships with multiple health systems in order to meet a current and growing demand for palliative care and hospice services, the exclusivity requirement makes it difficult for these physicians to easily participate in multiple ACOs.

A commenter representing specialty code 03 requested exclusion of specialty code 03 from step 2, indicating that allergy and immunology physicians are

not primary care physicians for the vast majority of patients they serve.

A commenter requested that infectious disease physicians (specialty code 44) be excluded from step 2 of the beneficiary assignment process in the final rule. The commenter stated these specialists would not typically provide primary care and that these specialists should be free to participate in multiple ACOs as, often times, they visit multiple hospitals and their clinical practice can span wide geographies. Other commenters requested that gastroenterology (specialty code 10), rheumatology (specialty code 66) and interventional cardiology (C3) be excluded from step 2, indicating that these specialists typically provide specialty care and would not routinely provide primary care.

Response: Our intent under the proposal was to exclude primary care service codes submitted by physician specialties that will very rarely, if ever, provide true primary care to beneficiaries. We continue to believe that the exclusion of such claims from determining the ACO's assigned population will result in more accurately assigning beneficiaries to ACOs based on where beneficiaries receive a plurality of true primary care services. However, after reviewing comments, we have determined that we need to modify our proposed policy. Specifically, we agree with the commenters who suggested that we consider the recommendations submitted by individual specialty organizations to revise the specialties to be included in step 2, because in general specialty organizations are knowledgeable about the types of services that the specialists provide, as well as the typical types of organizational relationships that such specialists have established. Therefore, if we received support for a specialty specific proposal listed in Table 2 or 3 of the proposed rule (79 FR 72796 and 72797), or at least received no objection from an affected specialty organization, then we are finalizing our specialty proposal. If a specialty society requested a revision to our proposals listed in Tables 1 through 4 of the proposed rule (79 FR 72796 and 72797), then we have generally accepted their recommendation when feasible. Responses to the specialty specific comments requesting revisions to our proposals are as follows:

- We agree with comments that recommended that it would be appropriate to include pediatric medicine in step 1 assignment. We agree that pediatricians typically provide primary care for their patients. While

very few children are Medicare beneficiaries, we also believe it will be appropriate to include these physicians in step 1 of the assignment process in order to better align the Shared Savings Program assignment methodology with the primary care emphasis in other provisions of the Affordable Care Act; section 5501 of the Affordable Care Act includes pediatric medicine in the definition of "primary care practitioner."

- Because we agree that osteopaths frequently provide primary care services, we agreed with commenters that specialty code 12 (osteopathic manipulative medicine) should be included in Step 2 assignment. As requested, we have also corrected the specialty name in this final rule for specialty code 12.

- We agree with commenters that psychiatry and its subspecialties (CMS specialty codes 26, 27, 79, and 86) often provide a substantial proportion of primary care for certain patients and therefore should be included in Step 2 assignment. We agree that psychiatry is frequently the point of first contact for persons with undiagnosed conditions and that those persons with serious mental illness or substance abuse disorders or both may prefer to receive their total care from their psychiatrist rather than from primary care physicians.

- We agree with commenters who requested that the following specialties be added to the list of specialties to be excluded from step 2 assignment: allergy and immunology (specialty code 03); gastroenterology (specialty code 10); infectious diseases (specialty code 44); rheumatology (specialty code 66); and interventional cardiology (C3). We agree that these specialists typically provide specialty care and do not routinely provide primary care for the vast majority of patients they serve. Despite their use of the same office visit codes that are included in the definition of primary care services under § 425.20, we agree with the commenters that these specialties do not routinely furnish primary care and furthermore, are not seen by patients as serving in a primary care role.

- We agree with commenters who requested that hospice and palliative medicine physicians (specialty code 17) should also be excluded from step 2 assignment. We note that certain physician services furnished to beneficiaries receiving services under the hospice benefit are paid through the Part A Hospice benefit and are not paid under the PFS. (See, for example, Medicare Claims Processing Manual, Chapter 11—Processing Hospice

Claims). This could make it difficult to determine for such beneficiaries, based on analysis of PFS claims, whether an ACO is actually providing the plurality of primary care service and managing the patient's overall care. At this time, we agree with commenters that hospice and palliative medicine physicians (specialty code 17) should be excluded from step 2. We emphasize that we are not excluding beneficiaries in Hospice from assignment to ACOs. However, we will not use services furnished by specialty code 17 to help determine beneficiary assignment. We believe this approach will still provide an incentive for ACOs to work with physicians furnishing palliative care and hospice care. We will consider these issues further and we may request additional comments in a future rulemaking on ways to assign beneficiaries receiving services under the Hospice benefit to the ACO or other entity that is actually providing primary care and managing the patient's overall care.

Therefore, we are finalizing our proposal to exclude services provided by certain physician specialties with the exception of these modifications. We believe the resulting step 2 exclusion list is limited to those physician specialties that will rarely, if ever, provide primary care to beneficiaries. We do not expect that the exclusion of these specialties from step 2 will have a significant impact on the overall number of beneficiaries assigned to each ACO because we believe the specialties that we are excluding from the assignment methodology provide a relatively modest number of services under the codes included in the definition of primary care services or are not typically the only physician who a beneficiary sees. For example, patients who are furnished consultations by a thoracic surgeon will typically also concurrently receive care from a primary care physician, cardiologist or other medical specialist.

The primary benefit of this final policy is that it will help correctly assign beneficiaries to the ACO or other entity that is actually providing primary care and managing the patient's overall care. Otherwise, for example, a beneficiary could inadvertently be assigned to an ACO based on services furnished by a surgeon who had not provided primary care but had provided a number of consultations for a specific clinical condition. Another important benefit of this policy is that any ACO participants who submit claims solely for services performed by the categories of specialists that we are excluding from the assignment process will have greater flexibility to participate in more than

one ACO. This could especially be the case for small physician practices that only submit claims for specialty services. Allowing such ACO participants who are composed solely of excluded specialists to participate in more than one ACO will support our goal of facilitating competition among ACOs by increasing the number of specialists who can participate in more than one ACO. ACO participant TINs that submit claims for primary care services that are used in our assignment methodology must continue to be exclusive to one Shared Savings Program ACO for purposes of beneficiary assignment.

Comment: A few commenters believe that CMS has applied assignment exclusivity more broadly than we had indicated in the 2011 final rule, and that we have effectively precluded any practice, regardless of specialty, that bills for E&M services from full-fledged participation in more than one ACO. Another commenter requested that previously issued guidance on how Medicare enrolled TINs could join with multiple ACOs as “other entities”, instead of as exclusive ACO participants, be formalized to ease ACOs’ reservations about entering into shared savings contracts with “other entities.” Specifically, the commenter urged CMS to formalize the principle that such other entities that are not ACO participants or ACO providers/suppliers may share in an ACO’s savings if the arrangement advances the ACO’s goals of increased care coordination, improved quality, and more efficient care delivery. A commenter requested that CMS provide clarity on how specialists that are excluded from the ACO beneficiary assignment process can participate in multiple ACOs and how we will ensure that administrative errors are avoided. The commenter is concerned that solo practitioners and single specialty practices will encounter problems if it is discovered that their TINs are associated with multiple ACOs.

Response: We have been consistent in our application of the requirement that ACO participants that submit claims for primary care services that are considered in the assignment methodology must be exclusive to a single ACO. We are finalizing our proposed changes to § 425.306(b) to clarify that each ACO participant who submits claims for primary care services used to determine the ACO’s assigned population must be exclusive to one Shared Savings Program ACO. Specifically, under § 425.306(b), the requirement that an ACO participant must be exclusive to a single ACO

applies whenever the ACO’s beneficiary assignment is dependent on that TIN, or in other words, when the primary care service claims submitted by the ACO participant are used to determine the ACO’s assigned population. The application of the exclusivity requirement to an ACO participant is not affected by whether or not a FFS beneficiary for whom an ACO participant has submitted claims for primary care services is ultimately assigned to the ACO. Retrospective reconciliation occurs at the end of the performance year, so an ACO participant will not know with certainty whether it has to be exclusive to a single ACO during a particular performance year if the requirement were dependent on which beneficiaries ultimately got assigned to the ACO. Rather, an ACO participant that submits claims to Medicare for primary care services must be exclusive to a single ACO because the claims for primary care services submitted by the ACO participant are used to determine beneficiary assignment to the ACO. Additionally, the exclusivity requirement is not affected by whether or not the primary care services for which the ACO participant submits claims are services furnished by primary care physicians, specialist physicians, or NPs, PAs, and CNSs. Furthermore, this exclusivity requirement applies only to the ACO participant TIN and not to individual practitioners, and only for purposes of assignment. For example, if a two person group submitted claims for services furnished by a physician specialist excluded from assignment and also submitted claims for primary care services furnished by a PA, then this group will still need to be exclusive to one ACO since the group’s claims are being used for assignment. Individual practitioners are free to participate in multiple ACOs, provided they are billing under a different Medicare-enrolled TIN for each ACO in which they participate. (See 76 FR 67810 through 67811). For example, there may be practitioners who work in multiple settings and bill Medicare for primary care services through several different TINs, depending on the setting. If each of these TINs represents an ACO participant in a different ACO, then the practitioner will be an ACO professional in more than one ACO.

Previously, we also issued guidance on how Medicare-enrolled TINs could join with multiple ACOs as “other entities” (see FAQ numbers 8 through 13 at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/FAQ.html#ACO_

Participant TIN Exclusivity and Other Entities). “Other entities” do not appear on the certified list of ACO participants and they are not used for program operations such as assignment. Therefore, they are not required to be exclusive to a single Shared Savings Program ACO. Entities that are not ACO participants or ACO providers/suppliers may share in an ACO’s savings if the arrangement advances the ACO’s goals of increased care coordination, improved quality, and more efficient care delivery. ACOs and ACO participants negotiate these arrangements individually. Although we are not providing additional guidance in this final rule regarding such other entities, we will continue to review this issue and intend to develop additional educational material to address specific questions raised as needed.

Comment: A commenter stated that assignment of beneficiaries to an ACO violates the beneficiary’s freedom of choice of provider. A few other commenters recommended that CMS clearly explain to beneficiaries that alignment (that is, assignment) to an ACO does not alter a beneficiary’s Medicare rights or consumer protections, including the freedom to choose a Medicare-enrolled provider that is outside the ACO.

Response: As noted previously, the statute requires the Secretary to determine an appropriate method to assign beneficiaries to ACOs on the basis of primary care services furnished to them by physicians. The term “assignment” for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care providers and suppliers from whom they receive their services. Likewise, the requirement that ACO participants that furnish primary care services used for assignment must be exclusive to a single ACO does not in any way imply that beneficiaries are locked into receiving services or referrals from specific ACO providers/suppliers. This point is also emphasized in educational materials for ACOs and beneficiaries.

Comment: A number of commenters suggested a very wide variety of alternative beneficiary assignment approaches for CMS to consider that would allow for ACO and provider choice. Some commenters suggested that CMS create a process by which each individual ACO could specifically identify the specialty/subspecialty physicians to include in its beneficiary assignment. A commenter suggested a different approach to determining the

inclusion and exclusion of certain providers in which we would delineate new criteria that more accurately pinpoint high cost, high risk, high need patients for whom continuity with certain providers is important. In the spirit of beneficiary empowerment and to support the concept of continuity of care, a commenter suggested that CMS should consider implementing a way for beneficiaries to affirm up front, that is to attest, the individual they believe to be “their doctor.” This would not limit patients from exercising provider choice going forward, but would allow patients to influence at least some part of patient attribution to the extent they have a relationship that is important to them.

A few other commenters suggested that assignment should be based on an alternative precedence or a weighting of the specific services included within the definition of primary care services. For example, a commenter suggested the first tier assignment should be with the use of the welcome to Medicare visit (G0402), the initial wellness exam (G0438), subsequent wellness exam (G0439), the CCM codes (99490) and TCM codes (99495 and 99496). Another the commenter suggested that assignment should be based on the number of “touches” the ACO has with the beneficiary which would outweigh the cumulative cost of services (that is, allowed charges) as the methodology for determining the plurality of primary care services for assignment purposes. The commenter indicated commercial payers have developed an ACO attribution methodology with which CMS should consider aligning, where the preponderance of care services (not necessarily cumulative cost) is used to assign patients.

Response: We appreciate these suggestions. However, in some cases, we do not believe that these suggestions are operationally feasible as it is not possible to implement the new processes that would be necessary to allow for individual ACO or provider choice or both at this time. We believe it would be burdensome on both ACOs and CMS to collect and maintain this information. Also, we have gained experience with our current method in the Physician Group Practice Demonstration, where it was well accepted (see <http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Medicare-Demonstrations-Items/CMS1198992.html>). Furthermore, we have adopted a similar beneficiary assignment approach for some other major programs, including the PQRS Group Practice Reporting Option via the GPRO web interface (77 FR 69195

through 69196) and the Value Modifier (VM) (79 FR 67790 and 79 FR 67962). In addition, the effect of these alternative approaches on ACOs, ACO participants, and ACO providers/suppliers is uncertain. However, we note that we plan for future rulemaking to allow for a method to incorporate beneficiary attestation into the assignment methodology as described in section II.F.7.b.(1). of this final rule.

We believe the revisions to the assignment methodology that we are finalizing in this rule will result in more accurate assignment of beneficiaries to ACOs based on where beneficiaries receive the plurality of true primary care services, while continuing to recognize that in some cases specialist physicians often take the role of primary care physicians in the overall treatment of the beneficiaries if there is no primary care physician or non-physician practitioner serving in that role.

FINAL ACTION: We are modifying our proposal to exclude services provided by certain physician specialties based on public comment, as follows:

- To include pediatric medicine (specialty code 37) in step 1 assignment.
- To include osteopathic manipulative medicine (specialty code 12) and psychiatry specialties (specialty codes 26, 27, 79, 86) in step 2 assignment.
- To exclude allergy and immunology (specialty code 03), gastroenterology (specialty code 10), hospice and palliative medicine (specialty code 17), infectious diseases (specialty code 44), rheumatology (specialty code 66), and interventional cardiology (C3) from step 2 assignment.

More specifically, the following four tables display the specific CMS physician specialty codes that are now included and excluded for beneficiary assignment purposes under the Shared Savings Program.

- Table 2 of this final rule shows the CMS physician specialty codes that are included in step 1 under the final policy.

- Table 3 of this final rule shows the CMS specialty codes for NPs, PAs, and CNSs that are included in beneficiary assignment step 1 under the final policy.

- Table 4 of this final rule lists the physician specialties that are included in step 2 under the final policy.

- Table 5 of this final rule lists the physician specialties that are excluded from the beneficiary assignment methodology under step 2 under the final policy. Services furnished by these physician specialties are also excluded for purposes of determining if a

beneficiary has received a primary care service from a physician who is an ACO professional, which under § 425.402(a) is a precondition for assignment to an ACO.

TABLE 2—SPECIALTY CODES INCLUDED IN ASSIGNMENT STEP 1

Code	Specialty name
01	General Practice.
08	Family Practice.
11	Internal Medicine.
37	Pediatric Medicine.
38	Geriatric Medicine.

TABLE 3—CMS NON-PHYSICIAN SPECIALTY CODES INCLUDED IN ASSIGNMENT STEP 1

Code	Specialty name
50	Nurse practitioner.
89	Clinical nurse specialist.
97	Physician assistant.

TABLE 4—PHYSICIAN SPECIALTY CODES—INCLUDED IN ASSIGNMENT STEP 2

Code	Specialty name
06	Cardiology.
12	Osteopathic manipulative medicine.
13	Neurology.
16	Obstetrics/gynecology.
23	Sports medicine.
25	Physical medicine and rehabilitation.
26	Psychiatry.
27	Geriatric psychiatry.
29	Pulmonary disease.
39	Nephrology.
46	Endocrinology.
70	Multispecialty clinic or group practice.
79	Addiction medicine.
82	Hematology.
83	Hematology/oncology.
84	Preventive medicine.
86	Neuro-psychiatry.
90	Medical oncology.
98	Gynecology/oncology.

TABLE 5—PHYSICIAN SPECIALTY CODES EXCLUDED FROM ASSIGNMENT STEP 2

Code	Specialty name
02	General surgery.
03	Allergy/immunology.
04	Otolaryngology.
05	Anesthesiology.
07	Dermatology.
09	Interventional pain management.
10	Gastroenterology.
14	Neurosurgery.

TABLE 5—PHYSICIAN SPECIALTY CODES EXCLUDED FROM ASSIGNMENT STEP 2—Continued

Code	Specialty name
17	Hospice and Palliative Care.
18	Ophthalmology.
20	Orthopedic surgery.
21	Cardiac electrophysiology.
22	Pathology.
24	Plastic and reconstructive surgery.
28	Colorectal surgery.
30	Diagnostic radiology.
33	Thoracic surgery.
34	Urology.
36	Nuclear medicine.
40	Hand surgery.
44	Infectious disease.
66	Rheumatology.
72	Pain management.
76	Peripheral vascular disease.
77	Vascular surgery.
78	Cardiac surgery.
81	Critical care (intensivists).
85	Maxillofacial surgery.
91	Surgical oncology.
92	Radiation oncology.
93	Emergency medicine.
94	Interventional radiology.
99	Unknown physician specialty.
C0	Sleep medicine.
C3	Interventional Cardiology.

We are finalizing our proposal to amend § 425.402 by adding a new paragraph (c) to identify the physician specialty designations that will be considered in step 2 of the assignment process, with the modifications noted previously. We are also finalizing the proposed modification to the exclusivity requirement at § 425.306(b) to clarify how the exclusivity rules will be affected by our final policy of excluding certain specialists from step 2 of the assignment methodology. Specifically, we are revising § 425.306(b) to clarify that each ACO participant who submits claims for primary care services used to determine the ACO’s assigned population must be exclusive to one Shared Savings Program ACO.

The current assignment methodology will continue to be used for PY 2015, including the final retrospective reconciliation which will occur in mid-2016, while the new methodology will be used for operations related to PY 2016, including during application review for ACOs that are applying or renewing for a 2016 start date. Thus, we have retained the rules for the current methodology under § 425.402(a) and the methodology that will be applicable for performance years beginning in 2016 has been designated under § 425.402(b) and (c). We did not receive any comments that directly addressed our proposal to make several conforming

and technical changes to § 425.402(a), and we are finalizing them with modifications to accommodate the revisions necessary to retain the current assignment methodology for PY 2015. Therefore, we clarify that the conforming and technical changes are reflected in §§ 425.402(a) and (b).

(3) Other Assignment Methodology Considerations

Finally, we note that in the proposed rule we considered another alternative approach to assignment. We considered whether it might be preferable, after excluding the specialties listed in Table 3 of the proposed rule from step 2 of the assignment process, to further simplify beneficiary assignment by establishing an assignment process that involves only a single step in which the plurality of primary care services provided by the physicians listed in Tables 1 and 2 of the proposed rule, and the non-physician practitioners in Table 4 of the proposed rule, would all be considered in a single step. (See 79 FR 72798). However, while it had some attractive features, we also expressed some important concerns about this approach. For example, beneficiaries receiving concurrent care from both primary care physicians and specialists could inappropriately be assigned to an ACO or other entity that is not responsible for managing their overall care. Therefore, we expressed a concern that by establishing an assignment methodology based on a single step, we might reduce our focus on primary care and ultimately assign some beneficiaries to an ACO inappropriately based on specialty care over true primary care. A one-step assignment methodology could also introduce additional instability into the assignment process. Therefore, we did not propose to combine the two steps used under the current assignment methodology.

Although we did not propose this change, we sought comments as to whether it would be preferable, after excluding the physician specialties listed in Table 3 (79 FR 72797) from the assignment process, to further simplify the assignment methodology by establishing an assignment process that involves only a single step.

We also welcomed any comments about the possible impact these potential changes to the assignment methodology might have on other CMS programs that use an assignment methodology that is generally aligned with the Shared Savings Program, such as PQRS GPRO reporting via the GPRO web interface and VM. We noted that, as previously discussed, we revised the assignment methodology for PQRS

GPRO reporting via the GPRO web interface and VM in the CY 2015 PFS final rule with comment period that appeared in the November 13, 2014 **Federal Register** (79 FR 67790 and 79 FR 67962).

Comment: A few commenters addressed the desirability of establishing a one-step assignment methodology. Most of these supported maintaining the current two-step assignment process. These commenters were concerned that adopting a one-step assignment process could inappropriately reduce the focus on primary care. A few commenters supported further examination of the issue for future consideration. A commenter suggested that assignment should be solely based on the preponderance of “evaluation and management services” provided regardless of specialty because most doctors are able to bill these codes. Otherwise, the commenter noted that the assignment determination is arbitrary, because it assumes all services provided by the “approved” specialties and even true primary care physicians are all related to primary care services, which they are not. This commenter stated that commercial payers are already recognizing this and developing attribution methods accordingly.

Response: We agree with commenters that it is appropriate to continue to maintain the current two-step assignment process at this time. We do not agree with commenters that believe a two-step methodology is arbitrary. We believe that the revisions to the beneficiary assignment methodology included in this final rule will further strengthen our balanced assignment process, which simultaneously maintains the requirement to focus on primary care services in beneficiary assignment, while recognizing the necessary and appropriate role of specialists in providing primary care services, such as in areas with primary care physician shortages.

Comment: A commenter was in support of the changes to the assignment methodology, including removing certain specialists from step 2 but recommended that CMS allow an ACO to continue to include physician and non-physician providers who are not used in the assignment methodology on the ACO’s annual, certified list of ACO providers/suppliers and consider all TINs and individual providers included on the list to meet PQRS GPRO reporting requirements through ACO reporting.

Response: Although not all providers and suppliers may provide services that are used to determine the assignment of

beneficiaries to an ACO, we believe that each of these entities has a role to play in the coordination of the care of FFS beneficiaries assigned to the ACO. For this reason, as discussed in section II.B.3. of this final rule, each NPI that has reassigned his or her billings to the TIN of the ACO participant must agree to participate and comply with program rules. Additionally, it is required that the ACO maintain and submit its list of ACO participants and ACO providers/suppliers in accordance with § 425.118. If not all providers and suppliers billing through the TIN have agreed to participate in the ACO and to comply with the program requirements, the ACO cannot add the ACO participant to its list. Therefore, ACOs must include all physicians and non-physician providers who bill under the TIN of an ACO participant on their annual, certified list of ACO providers/suppliers even if their services are not used in the assignment methodology.

FINAL ACTION: We appreciate the comments and will continue to consider them when developing future rules.

5. Assignment of Beneficiaries to ACOs That Include FQHCs, RHCs, CAHs or ETA Hospitals

In this section, we summarize the regulatory policies in § 425.404 for assignment of beneficiaries to ACOs that include FQHCs and RHCs as ACO participants and subsequent operational procedures and instructions that we have established in order to allow FQHCs and RHCs as well as CAHs billing under section 1834(g)(2) of the Act (referred to as Method II), and ETA hospitals to fully participate in the Shared Savings Program. These types of providers may submit claims for physician and other professional services when certain requirements are met, but they do not submit their claims through the standard Part B claims payment system. Accordingly, we have established operational processes so that we can consider claims for professional services submitted by these providers in the process for assigning beneficiaries to ACOs. However, each of these four provider types (that is, FQHCs, RHCs, CAHs, and ETA hospitals) generally have differing circumstances with respect to their provider and medical service code reporting requirements, claims forms used, and the payment methodology that applies to professional services. Although there are important differences between the payment policy and claims processing for FQHCs and RHCs, they do share some key characteristics. Therefore, we will discuss FQHCs and RHCs jointly,

and then address CAHs and ETA hospitals separately.

a. Assignment of Beneficiaries to ACOs That Include FQHCs and RHCs

(1) Overview

FQHCs and RHCs are facilities that furnish services that are typically furnished in an outpatient clinic setting. (See the proposed rule at 79 FR 72798 and 72799.) They are currently paid an all-inclusive rate (AIR) per visit for qualified primary and preventive health services furnished to Medicare beneficiaries. On October 1, 2014, FQHCs began to transition to a new FQHC prospective payment system (PPS). FQHCs have been required to use HCPCS coding on all their claims since January 1, 2011, to inform the development of the PPS and for limited other purposes, and will be required to use HCPCS coding for payment purposes under the FQHC PPS.

Based on detailed comments from some FQHC and RHC representatives, in the November 2011 final rule, we established a beneficiary assignment process that allows primary care services furnished in FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC or RHC as an ACO participant. This process is codified in the regulations at § 425.404. Operationally we assign beneficiaries to ACOs that include FQHCs or RHCs in a manner generally consistent with how we assign beneficiaries to other ACOs based on primary care services performed by physicians as described previously. However, to address the requirement under section 1899(c) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians, we require ACOs that include FQHCs or RHCs to identify, through an attestation (see § 425.404(a)), the physicians that provide direct patient primary care services in their ACO participant FQHCs or RHCs. We use the combination of the FQHC or RHC ACO participant TIN (and other unique identifier such as CCN, where appropriate) and the NPIs of the FQHC or RHC physicians provided to us through an attestation process to identify those beneficiaries who received a primary care service from a physician in the FQHC or RHC and who are therefore eligible to be assigned to the ACO as provided under § 425.402(a)(1). Then, we assign those beneficiaries to the ACO, using the step-wise assignment methodology under § 425.402(a)(1) and (2), if they received the plurality of their primary care

services, as determined based on allowed charges for the HCPCS codes and revenue center codes included in the definition of primary care services at § 425.20, from ACO professionals.

The special procedures that we have established in the November 2011 final rule and through operational program instructions are discussed in detail in the proposed rule (79 FR 72799). FQHC and RHC services are billed on an institutional claim form and require special handling to incorporate them into the beneficiary assignment process. For FQHCs/RHCs that are ACO participants, we treat a FQHC or RHC service reported on an institutional claim as a primary care service performed by a primary care physician if the claim includes a HCPCS or revenue center code that is included in the definition of a primary care service at § 425.20 and the service was furnished by a physician who was identified as providing direct primary care services on the attestation submitted as part of the ACO's application. All such physicians are considered primary care physicians for purposes of the assignment methodology and no specialty code is required for these claims. If the claim is for a primary care service furnished by someone other than a physician listed on the attestation, we treat the service as a primary care service furnished by a non-physician ACO professional.

For FQHCs/RHCs that are not ACO participants, we assume a primary care physician performed all primary care services. We chose to assume such primary care services were furnished by primary care physicians so that these services would be considered in step 1 of the assignment methodology. We established this operational procedure to help make sure we do not disrupt established relationships between beneficiaries and their care providers in non-ACO participant FQHCs and RHCs by inappropriately assigning beneficiaries to ACOs that are not primarily responsible for coordinating their overall care.

(2) Proposed Revisions

As currently drafted, § 425.404(b) conflates the question of whether a service billed by an FQHC or RHC is provided by a physician with the question of whether the service is a primary care service. As a consequence, the provision arguably does not address situations where the FQHC/RHC claim is for a primary care service as defined under § 425.20, but the NPI reported on the claim is not the NPI of a physician included in the attestation submitted under § 425.404(a). Therefore, we

proposed to revise § 425.404(b) to better reflect the program rules and operational practices as previously outlined. In addition, we proposed to revise § 425.404(b) to reflect the proposal discussed earlier to revise § 425.402 to include services furnished by NPs, PAs, and CNSs as services that will be considered in step 1 of the assignment process. Under these proposals, we would assign beneficiaries to ACOs that include FQHCs and RHCs in the following manner.

To address the requirement under section 1899(c) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians, we would continue to require ACOs that include FQHCs and RHCs to identify, through an attestation process (see § 425.404(a)), the physicians who provide direct patient primary care services in their ACO participant FQHCs or RHCs. Under the proposal we would use this attestation information only for purposes of determining whether a beneficiary is assignable to an ACO because he or she meets the criteria of having received a primary care service from a physician the FQHC/RHC has designated on their attestation list. We refer to this determination under § 425.402(a) and (b)(1) as being the assignment “pre-step”. If a beneficiary is identified as an “assignable” beneficiary in the assignment pre-step, then we would use claims for primary care services furnished by all ACO professionals submitted by the FQHC or RHC in determining whether the beneficiary received a plurality of his or her primary care services from the ACO under Step 1. We proposed to make revisions to § 425.404(b) to reflect these policies.

We have also encountered instances where an assignable beneficiary has received primary care services from FQHCs or RHCs that are not participants in an ACO. For non-ACO participant FQHCs and RHCs, we have previously assumed that all of their primary care services are performed by primary care physicians. However, as discussed in the proposed rule (see 79 FR 72800) this special assumption for non-ACO FQHCs/RHCs would no longer be necessary under the proposed revision to the assignment methodology at § 425.402 to consider primary care services furnished by NPs, PAs, and CNSs in step 1 of the assignment methodology rather than step 2. Under this proposed revision, all primary care services furnished by non-ACO FQHCs/RHCs would be considered in step 1 of

the assignment methodology, and there would no longer be a need to assume such primary care services were provided by primary care physicians in order to achieve this result.

We welcomed comments on our proposed revisions to § 425.404(b) and our current procedures for using claims submitted by FQHCs and RHCs in the assignment methodology and suggestions on how we might further support participation of FQHCs and RHCs in the Shared Savings Program in a manner that is consistent with the statutory requirements.

Comment: Commenters agreed that CMS should recognize all FQHC/RHC care provided by PAs, NPs and CNSs as primary care. Commenters also agreed that if a beneficiary is identified as an “assignable” beneficiary in the assignment pre-step, then it is appropriate to recognize FQHC/RHC care provided by all ACO professionals under Step 1 assignment.

Response: We agree with these commenters. We believe it is important to clarify the rules to better reflect current operating procedures, and also to revise them to reflect the final policy discussed earlier to include services furnished by non-physician practitioners in step 1 of the assignment process.

Comment: A commenter supported including all ACO participant non-physician practitioners in the assignment process in step 1 but excluding any non-ACO participant non-physician practitioners during step 1 in order to facilitate assignment of beneficiaries receiving services at FQHCs/RHCs.

We disagree with the suggestion to include ACO participant non-physician practitioners during step 1 but to exclude claims billed under a non-ACO participant TIN by non-physician practitioners during step 1. We are concerned that this approach could lead to beneficiaries being assigned to an ACO, even if some other entity is primarily responsible for managing their care. This result would be contrary to our policy goal of assigning beneficiaries to the entity that is primarily responsible for their overall care.

Comment: A few commenters objected to the statutory requirement that beneficiaries be assigned on the basis of primary care services furnished by physicians, a requirement that is satisfied by the pre-step in CMS’ assignment methodology.

Response: As discussed earlier in this section, the pre-step is designed to satisfy the statutory requirement under section 1899(c) of the Act that

beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians. We refer to this determination under § 425.402(a)(1) and (b)(1) as being the assignment “pre step”. We must retain the pre-step as part of the assignment methodology in order to comply with the requirements of section 1899(c) of the Act.

FINAL ACTION: We are finalizing our proposal to amend § 425.404 to use FQHC/RHC physician attestation information only for purposes of determining whether a beneficiary is eligible to be assigned to an ACO. If a beneficiary is identified as “assignable” then we will use claims for primary care services furnished by all ACO professionals submitted by the FQHC or RHC to determine whether the beneficiary received a plurality of his or her primary care services from the ACO under Step 1. We recognize the unique needs and challenges of rural communities and the importance of rural providers in assuring access to health care. FQHCs, RHCs and other rural providers play an important role in the nation’s health care delivery system by serving as safety net providers of primary care and other health care services in rural and other underserved areas and for low-income beneficiaries. We have attempted to develop and implement regulatory and operational policies to facilitate full participation of rural providers in the Shared Savings Program, within the statutory requirements for the program.

b. Assignment of Beneficiaries to ACOs That Include CAHs

In the proposed rule (see 79 FR 72801) we briefly addressed certain issues regarding ACOs that include CAHs billing under section 1834(g)(2) of the Act (referred to as method II). Professional services billed by method II CAHs are reported using HCPCS/CPT codes and are paid using a methodology based on the PFS. However, method II CAH claims that include professional services require special processing because they are submitted as part of institutional claims. Therefore, we have developed operational procedures that allow these claims to be considered in the assignment process under § 425.402. Although we did not make any new proposals regarding the use of services billed by method II CAHs in the assignment process, we noted that our procedures for incorporating claims billed by method II CAHs into the assignment methodology are available on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/>

Downloads/Shared-Savings-Losses-Assignment-Spec-v2.pdf (see section 3.3.)

Comment: A few commenters supported the process for using claims billed by method II CAHs in the assignment methodology.

Response: We appreciate the supportive comments. We did not make any new proposals regarding the assignment of beneficiaries receiving primary care services furnished by method II CAHs but included this discussion in the proposed rule to promote understanding of our processes.

FINAL ACTION: We will continue including claims for primary care services billed by method II CAHs in the beneficiary assignment process under § 425.402 using established procedures.

c. Assignment of Beneficiaries to ACOs That Include ETA Hospitals

In the proposed rule (79 FR 72801 and 72802), we discussed in detail the operational procedures that we have established in order to include primary care services performed by physicians at ETA hospitals in the assignment of beneficiaries to ACOs. ETA hospitals are hospitals that, under section 1861(b)(7) of the Act and § 415.160 of our regulations, have voluntarily elected to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in lieu of Medicare PFS payments that might otherwise be made for these services. We have developed special operational instructions and processes (see 79 FR 72801 and 72802) that enable us to include primary care services performed by physicians at ETA hospitals in the assignment of beneficiaries to ACOs under § 425.402.

In summary, we use institutional claims submitted by ETA hospitals in the assignment process because ETA hospitals are paid for physician professional services on a reasonable cost basis through their cost reports and no other claim is submitted for such services. However, ETA hospitals bill us for their separate facility services when physicians and other practitioners provide services in the ETA hospital and the institutional claims submitted by ETA hospitals include the HCPCS code for the services provided. We use the HCPCS code included on this institutional claim to identify whether a primary care service was rendered to a beneficiary in the same way as for any other claim. These institutional claims do not include allowed charges, which are necessary to determine where a beneficiary received the plurality of primary care services as part of the

assignment process. Accordingly, we use the amount that would otherwise be payable under the PFS for the applicable HCPCS code, in the applicable geographic area as a proxy for the allowed charges for the service.

In the proposed rule, we explained that we believe it is appropriate that ETA hospitals and their patients benefit from the opportunity for ETA hospitals to fully participate in the Shared Savings Program to the extent feasible. Therefore, we proposed to revise § 425.402 by adding a new paragraph (c) to provide that when considering services furnished by physicians in ETA hospitals in the assignment methodology, we would use the amount payable under the PFS for the specified HCPCS code as a proxy for the amount of the allowed charges for the service. In addition, because we are able to consider claims submitted by ETA hospitals as part of the assignment process, we also proposed to amend § 425.102(a) to add ETA hospitals to the list of ACO participants that are eligible to form an ACO that may apply to participate in the Shared Savings Program.

We sought comments on the use of institutional claims submitted by ETA hospitals for purposes of identifying primary care services furnished by physicians in order to allow these services to be considered in the assignment of beneficiaries to ACOs. We also sought comments on whether there are any other types of potential ACO participants that submit claims representing primary care services that CMS should also consider including in (or excluding from) its methodology for assigning beneficiaries to ACOs participating in the Shared Savings Program.

Comment: A few commenters supported the proposal, pointing out that beneficiaries in medically underserved populations could benefit from the improved care coordination ACOs with ETA hospitals may provide. A commenter opposed the proposal but offered little explanation. A commenter requested clarification of how CMS would be modifying its operational processes for including primary care services performed by physicians in ETA hospitals to reflect a change in coding policy under the OPPS effective for services furnished on or after January 1, 2014. Effective January 1, 2014, CMS will recognize HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient) for payment under the OPPS for outpatient hospital clinic visits. Also, effective January 1, 2014, CPT codes 99201 through 99205 and 99211 through

99215 are no longer recognized for payment under the OPPS. Under the OPPS, outpatient hospitals were instructed to use HCPCS code G0493 in place of 99201 through 99205 and 99211 through 99215.

Response: Since the December 2014 proposed rule was issued, new information has come to light about how clinic visits are billed under OPPS, effective January 1, 2014. This change affects our operational processes for considering ETA hospital claims in the assignment methodology for the Shared Savings Program because under OPPS, outpatient hospitals including ETA hospitals, no longer report CPT codes in the range 99201 through 99205 and 99211 through 99215. Instead, as noted by the commenter, outpatient hospitals report all such services using a single HCPCS code, G0463. That is, for ETA hospitals, G0463 is a replacement code for CPT codes in the range 99201 through 99205 and 99211 through 99215. Therefore, we need to further consider our ETA proposal and will address this coding issue in future rulemaking. We continue to believe that it is appropriate to use ETA institutional claims for purposes of identifying primary care services furnished by physicians in ETA hospitals in order to allow these services to be included in the stepwise methodology for assigning beneficiaries to ACOs. We believe that including these claims increases the accuracy of the assignment process by helping to ensure that beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary's care. ETA hospitals are often located in underserved areas and serve as providers of primary care for the beneficiaries they serve.

FINAL ACTION: We will further consider the operational processes necessary in order to allow ETA hospital outpatient claims to continue to be considered in the assignment methodology and will address these issues in future rulemaking

6. Applicability Date for Changes to the Assignment Algorithm

As indicated in the **DATES** section of this final rule, the effective date for the final rule will be 60 days after the final rule is published. However, we proposed that any final policies that affect beneficiary assignment would be applicable starting at the beginning of the next performance year. We stated that implementing any revisions to the assignment methodology at the beginning of a performance year is reasonable and appropriate because it would permit time for us to make the necessary programming changes and

would not disrupt the assessment of ACOs for the current performance year. Moreover, we proposed to adjust all benchmarks at the start of the first performance year in which the new assignment rules are applied so that the benchmark for an ACO reflects the use of the same assignment rules as would apply in the performance year. For example, any new beneficiary assignment policies that might be included in a final rule issued in 2015 would apply to beneficiary assignment starting at the beginning of the following performance year, which in this example would be January 1, 2016. In this hypothetical example, we would also adjust performance benchmarks that apply for the 2016 and subsequent performance years, as applicable, to reflect changes in our assignment methodology.

In addition, under the proposal we would not retroactively apply any new beneficiary assignment policies to a previous performance year. For example, if the assignment methodology is applied beginning in 2016, we would not use it in mid-2016 to reconcile the 2015 performance year. Accordingly, the assignment methodology used at the start of a performance year would also be used to conduct the final reconciliation for that performance year.

Comment: Commenters agreed with the proposal to adjust benchmarks at the start of the first performance year in which the new assignment rules are applied so that the benchmark for the ACO reflects the use of the same assignment rules as would apply in the performance year.

Response: We agree and believe uniformly applying any change to the assignment methodology at the beginning of a performance year will mitigate disruptions in implementing changes in the beneficiary assignment policies.

FINAL ACTION: We are finalizing our proposal to adjust all benchmarks at the start of the first performance year in which the new assignment rules are applied so that the benchmark for the ACO reflects the use of the same assignment rules as will apply in the performance year. Additionally, we will not retroactively apply the new beneficiary assignment methodology to the previous performance year. In other words, when conducting the final retrospective reconciliation of beneficiary assignment for PY 2015 during mid-2016, we will use the assignment methodology that was applicable at the start of 2015.

F. Shared Savings and Losses

1. Background

Section 1899(d) of the Act establishes the general requirements for payments to participating ACOs. Specifically, section 1899(d)(1)(A) of the Act provides that ACO participants will continue to receive payment “under the original Medicare fee-for-service program under parts A and B in the same manner as they would otherwise be made,” and that an ACO is eligible to receive payment for shared Medicare savings provided that the ACO meets both the quality performance standards established by the Secretary, and demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures. Additionally, section 1899(i)(3) of the Act authorizes the Secretary to use other payment models in place of the one-sided model outlined in section 1899(d) of the Act as long as the Secretary determines these other payment models will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

In our November 2011 final rule (76 FR 67904 through 67909) establishing the Shared Savings Program, we considered a number of options for using this authority. For example, commenters suggested we consider such options as blended FFS payments, prospective payments, episode/case rate payments, bundled payments, patient centered medical homes or surgical homes payment models, payments based on global budgets, full or partial capitation, and enhanced FFS payments for care management. However, in the November 2011 final rule (76 FR 67905), we opted not to use our authority under section 1899(i) of the Act to integrate these kinds of alternative payment models at that time, noting that many of the suggested payment models were untested. We expressed concern that immediately adopting untested and/or unproven models with which we had little experience on a national scale could lead to unintended consequences for the FFS beneficiaries we serve or for the health care system more broadly. We also noted that the Affordable Care Act had established a new Center for Medicare and Medicaid Innovation (Innovation Center) at CMS. The Innovation Center is charged with developing, testing, and evaluating innovative payment and service delivery models in accordance with the requirements of section 1115A of the Act. Many of the approaches suggested by stakeholders and commenters on the

Shared Savings Program rule are the subject of ongoing testing and evaluation by the Innovation Center. In the November 2011 final rule (76 FR 67905), we noted that while we did not yet have enough experience with novel payment models to be comfortable integrating them into the Shared Savings Program at the time, we anticipated that what we learned from these models might be incorporated into the program in the future. Since publication of the December 2014 proposed rule, the Innovation Center has announced several important developments related to its testing of ACO models. In May 2015, the Secretary announced that an independent evaluation report for CMS found that the Pioneer ACO Model generated over \$384 million in savings to Medicare over its first 2 years—an average of approximately \$300 per assigned beneficiary per year—while continuing to deliver high-quality patient care. The CMS Office of the Actuary certified the Pioneer ACO model, as tested during the first 2 performance years of the Model, to have met the criteria for expansion to a larger population of Medicare beneficiaries. See News release “Affordable Care Act payment model saves more than \$384 million in 2 years, meets criteria for first-ever expansion” (May 4, 2015) available online at <http://www.hhs.gov/news/press/2015pres/05/20150504a.html>. In March 2015, the Innovation Center announced the launch of the Next Generation ACO Model, whose first performance year begins January 1, 2016, building upon experiences from the Pioneer ACO Model and the Medicare Shared Savings Program. The Next Generation ACO Model uses refined benchmarking methods that reward both attainment and improvement in cost containment, and that ultimately transition away from comparisons to an ACO’s historical expenditures. The Model also offers a selection of payment mechanisms to enable ACOs to progress from FFS reimbursements to capitation. Central to the Next Generation ACO Model are several “benefit enhancement” tools to help ACOs improve engagement with beneficiaries, including:

- Greater access to home visits, telehealth services, and skilled nursing facility services;
- Opportunities to receive a reward payment for receiving care from the ACO and certain affiliated providers;
- A process that allows beneficiaries to confirm their care relationship with ACO providers; and
- Greater collaboration between CMS and ACOs to improve communication

with beneficiaries about the characteristics and potential benefits of ACOs in relation to their care.

In the November 2011 final rule establishing the Shared Savings Program (76 FR 67909), we created two tracks from which ACOs could choose to participate: A one-sided risk model (Track 1) that incorporates the statutory payment methodology under section 1899(d) of the Act and a two-sided model (Track 2) that is also based on the payment methodology under section 1899(d) of the Act, but incorporates performance-based risk using the authority under section 1899(i)(3) of the Act to use other payment models. Under the one-sided model, ACOs qualify to share in savings but are not responsible for losses. Under the two-sided model, ACOs qualify to share in savings with an increased sharing rate, but also must take on risk for sharing in losses.

In the November 2011 final rule (76 FR 67904), we explained that offering these two tracks would create an on ramp for the program to attract both providers and suppliers that are new to value-based purchasing as well as more experienced entities that are ready to share in losses. We stated our belief that a one-sided model would have the potential to attract a large number of participants to the program and introduce value-based purchasing broadly to providers and suppliers, many of whom may never have participated in a value-based purchasing initiative before. Another reason we included the option for a one-sided track with no downside risk was that this model would be accessible to and attract small, rural, safety net, and physician-only ACOs.

However, we also noted that while a one-sided model could provide incentives for participants to improve quality, it might not be sufficient incentive for participants to improve the efficiency and cost of health care delivery (76 FR 67904). Therefore, we used our authority under section 1899(i)(3) of the Act to create a performance-based risk option, Track 2, where ACOs would not only be eligible to share in savings, but also must share in losses. We believe a performance-based risk option would have the advantage of providing more experienced ACOs an opportunity to enter a sharing arrangement that provides greater reward for greater responsibility. During our initial rulemaking, we explained that both CMS and stakeholders believe that models where ACOs bear a degree of financial risk hold the potential to induce more meaningful systematic change. Therefore, the program's

policies were initially designed to offer a pathway for ACOs to transition from the one-sided model to risk-based arrangements. Therefore, we required that ACOs who participate in Track 1 during their first agreement period must transition to Track 2 for all subsequent agreement periods. We believe that offering the two tracks, but requiring a transition to Track 2 in subsequent agreement periods, would increase interest in the Shared Savings Program by providing a gentler "on ramp" while maintaining the flexibility for more advanced ACOs to take on greater performance-based risk in return for a greater share of savings immediately upon entering the program (76 FR 67907).

Although most of the program requirements that apply to ACOs in Track 1 and Track 2 are the same, the financial reconciliation methodology was designed so that ACOs that accept performance-based risk under Track 2 would have the opportunity to earn a greater share of savings. Thus, the same eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data sharing provisions, monitoring for avoidance of at-risk beneficiaries, provider screening, and transparency requirements apply to ACOs under both models. However, the financial reconciliation methodology was modified for Track 2 in order to allow an opportunity for ACOs to earn a greater share of savings, in exchange for their willingness to accept performance-based risk. Specific differences between the two tracks include the minimum savings rate (MSR), the sharing rate based on quality performance, and the performance payment limit.

In the December 2014 proposed rule, we reiterated our intent to continue to encourage ACOs' forward movement up the ramp from the one-sided model to performance-based risk. The proposed rule discussed policy changes that would both allow ACOs not yet ready to transition to performance-based risk a second agreement period under the one-sided model, while also encouraging ACOs to enter performance-based risk models by lowering the risk under the existing Track 2, and offering an additional two-sided model (Track 3). As proposed, Track 3 would be based on the current payment methodology under Track 2, but would also incorporate some different elements that may make it more attractive for entities to accept increased performance-based risk, including: Prospective beneficiary assignment, and greater risk for greater

reward (as compared to the current Track 2). We proposed modifications to the requirements for ACOs to establish an adequate repayment mechanism as a condition to participate under the two-sided model, including changes to address concerns that the existing requirements tie up capital that otherwise could be used to implement the care processes necessary to succeed in the program. We also sought comment on other ways to encourage ACO participation in performance-based risk arrangements, including the following:

- Waiving certain payment and program requirements.
- Incorporating beneficiary attestation, under which an eligible beneficiary would have the opportunity to voluntarily align with the ACO in which their primary healthcare provider participates.
- ACO participant arrangements which would allow ACOs to make a step-wise transition to performance-based risk arrangements.

Further, we sought comment on alternative methodologies for establishing, updating, and resetting ACO benchmarks based on concerns about the sustainability of the program under the current policies.

In this section, we discuss our final actions on the proposals for modifying the program's financial models, as well as the options on which we sought comment, including alternative benchmarking methodologies and potential policies to further encourage ACO participation in performance-based risk arrangements (for example, by waiving certain payment and program requirements and adopting beneficiary attestation). Table 8 summarizes the differences between the one-sided and two-sided models and specifies the characteristics of the Tracks as finalized under the November 2011 final rule and with this final rule.

2. Modifications to the Existing Payment Tracks

a. Overview

In the November 2011 final rule, we established policies to encourage ACOs not only to enter the program, but also to progress to increased risk based on the belief that payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in the behavior of providers and suppliers. Therefore, we established a requirement that an ACO entering the program under Track 1 may only operate under the one-sided model for its first agreement period. For subsequent agreement periods, an ACO would not be

permitted to operate under the one-sided model (§ 425.600(b)). If the ACO wishes to participate in the program for a second agreement period, it must do so under Track 2 (shared savings/losses). Additionally, an ACO experiencing a net loss during its initial agreement period may reapply to participate in the program, but the ACO must identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period (§ 425.600(c)). In our view, this allowance for a full first agreement period under the one-sided model and required transition to performance-based risk in the subsequent agreement period struck a balance between our intent to encourage program participation by small, rural, or physician-only ACOs with the need to ensure that ACOs quickly transition to taking downside risk.

We are encouraged by the popularity of the Shared Savings Program, particularly the popularity of the one-sided model. Most ACOs participating in the Shared Savings Program have chosen Track 1, with only 5 ACOs participating under Track 2 as a starting option. About half of the ACOs participating in the program are small, each having less than 10,000 assigned beneficiaries. In the December 2014 proposed rule we explained that we believe that one 3-year agreement period under Track 1 is sufficient for many organizations to progress along the on-ramp to performance-based risk. We reiterated that we continue to encourage forward movement up the ramp because we believe, as discussed in the November 2011 final rule (76 FR 67907), that payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in providers' and suppliers' behavior. However, based on our experience with the program, we recognized that many of the organizations that are currently participating in the program are risk averse and lack the infrastructure and readiness to manage increased performance-based risk. We explained that given the short time period between finalization of the November 2011 final rule and the first application cycles, it is our impression that many ACOs, particularly smaller ACOs, focused initially on developing their operational capacities rather than on the implementation of care redesign processes. We expressed some concerns about the slope of the on-ramp to performance-based risk created by the

two existing tracks and the policy that requires ACOs in Track 1 (shared savings only) to transition to Track 2 (shared savings/losses) for their second agreement period. In particular we explained our concern that the current transition from one- to two-sided risk may be too steep for some organizations, putting them into a situation where they must choose between taking on more risk than they can manage or dropping out of program participation altogether. For instance, some smaller and less experienced ACOs will likely drop out of the program when faced with this choice, because the smaller an ACO's assigned beneficiary population, the greater the chances that shared losses could result from normal variation. Also, we explained the concern, as expressed by some stakeholders, that one agreement period under the one-sided model may be not be a sufficient amount of time for some ACOs to gain the level of experience with population management or program participation needed for them to be comfortable taking on performance-based risk. For some organizations, having additional experience in the Shared Savings Program under Track 1 could help them to be in a better position to take on performance-based risk over time. We also expressed concern that the existing features of Track 2 may not be sufficiently attractive to ACOs contemplating entering a risk-based arrangement.

In the December 2014 proposed rule we revisited our policies related to Tracks 1 and 2 in order to smooth the on ramp for organizations participating in the Shared Savings Program. First, we proposed to remove the requirement at § 425.600(b) for Track 1 ACOs to transition to Track 2 after their first agreement period. Second, we proposed to modify the financial thresholds under Track 2 to reduce the level of risk that ACOs must be willing to accept. We explained that we believe there are a number of advantages to smoothing the on ramp by implementing these proposed policies as follows:

- Removing the requirement that ACOs transition to a two-sided model in their second agreement period would provide organizations, especially newly formed, less experienced, and smaller organizations, more time to gain experience in the program before accepting performance-based risk, thereby encouraging continued participation in the program by potentially successful ACOs that would otherwise drop out because of the requirement to transition to the two-sided model in their second agreement period.

- Allowing organizations to gain more experience under a one-sided model before moving forward to a two-sided model would encourage earlier adoption of the shared savings model by organizations concerned about being required to transition to performance-based risk before realizing savings under a one-sided model.

- Incorporating the opportunity for ACOs to remain in Track 1 after their first agreement period could have a beneficial effect with respect to the care that beneficiaries receive. Specifically, to the extent that more ACOs are able to remain in the program, a potentially broader group of beneficiaries will have access to better coordinated care through an ACO.

- Allowing ACOs additional time to make the transition to performance-based risk would reduce the chances that a high-performing ACO, which believe that it is not yet ready to assume greater financial risk, will either cease to participate in the program to avoid risk or find it necessary to engage in behaviors primarily intended to minimize that risk rather than improve patient care.

Further, we explained our expectation that ACOs participating in the Shared Savings Program move in the direction of accepting performance-based risk. Thus, while we proposed to offer additional time for ACOs under a one-sided model, we also indicated there should be incentives for participants to voluntarily take on additional financial risk and disincentives to discourage organizations from persisting in a shared savings only risk track indefinitely. To signal to ACOs the importance of moving toward performance-based risk and encourage ACOs to voluntarily enter the two-sided model as soon as they are able, we proposed to distinguish the financial attractiveness of the one-sided model from the two-sided model by dropping the sharing rate in Track 1 for ACOs participating in Track 1 for a subsequent agreement period and modifying the risk inherent in Track 2. Finally, we explained that adopting restrictions to prevent organizations that have not achieved certain minimum performance requirements with respect to cost and quality of care, based on their experience to date, from obtaining additional agreement periods under Track 1 would serve as an appropriate program safeguard against entities remaining in the program that are not fully committed to improving the quality and efficiency of health care service delivery. We received many comments regarding the overall framework we outlined in the proposed

rule for modifying the existing payment tracks under the Shared Savings Program.

Comment: Some commenters urged CMS to strengthen the program's existing financial tracks, suggesting alternatives that went beyond the modifications discussed in the December 2014 proposed rule. Some commenters pointed out that as designed, the program's existing financial models inadequately reward ACOs for the savings they generate, discourage ACOs who are working to achieve program goals, and pose hardships for ACOs who rely on shared savings payments to support their operational costs needed to sustain their participation in the program.

Some commenters explained that increasing the opportunity for savings under Track 1 is a means of encouraging continued program growth and sustainability of ACOs, and is a means for ensuring ACOs become ready to enter the two-sided model. Some commenters specifically addressed how to make performance-based risk arrangements under the program more attractive and to encourage ACOs to transition to risk, citing the importance of certain factors such as:

- Enhanced financial rewards, for example through a lower/fixed MSR, or eliminating the MSR, or revising the MSR methodology; higher sharing rates; and policies to reward ACOs who are trending positive (whose expenditures are lower than their benchmarks but who have not met or exceeded their MSR).

- Reduced liability for risk under the two-sided model, for example through a higher MLR, or lower loss sharing rates (that is, a phase-in to higher loss sharing rates over time), and lower loss limits (that is, a gentler phase-in of the loss limit by starting at zero and progressing to 10 percent).

- Tools to enable ACOs to more effectively control and manage their patient population, for example through prospective beneficiary assignment, beneficiary attestation, improved data sharing, and regulatory and programmatic flexibilities.

- Additional safeguards against risk, for instance in the form of CMS-subsidized stop loss insurance and funding for ACOs seeking to move to risk to make sure they have adequate cash reserves.

Commenters typically recommended a combination of these factors. Some commenters' recommendations were specific to certain types of entities. In particular, commenters recommended improving the financial incentives for

smaller ACOs, rural ACOs, and existing low-cost ACOs.

Several commenters underscored the need for ACOs to be successful in Track 1 before moving to two-sided risk. A commenter explained that ACOs should not be expected to participate in the Shared Savings Program with upside risk under Track 1 with one set of rules, but then undertake downside risk under a different set of rules. Along these lines, some commenters urged CMS to apply the same assignment methodology and allow the same regulatory and programmatic flexibilities under the one-sided model that apply to the two-sided model, explaining that doing so could: (1) allow Track 1 ACOs to gain experience with these program features before accepting risk under the same terms; (2) stimulate success within the program by Track 1 ACOs and allow them to more quickly move to a two-sided risk track; and (3) reduce administrative burden on CMS for implementing the program.

Some commenters supported policies that would allow ACOs to move from the one-sided to two-sided risk within a given agreement period. Several commenters suggested allowing ACOs to move from Track 1 to a two-sided risk track annually, so that ACOs ready to assume more risk do not have to wait until a new agreement period to change tracks. Several commenters recommending CMS move to 5 or 6 year agreements for ACOs suggested that ACOs have the opportunity to move to a performance-based risk model during their first agreement period, for example, after their first 3 years under the one-sided model. A commenter suggested encouraging ACOs to transition to two-sided risk by offering lower loss sharing rates for ACOs that move from Track 1 to the two-sided model during the course of an agreement period, and phasing-in loss sharing rates for these ACOs (for example, 15 percent in year 1, 30 percent in year 2, 60 percent in year 3). Another commenter suggested that CMS allow all ACOs (regardless of Track) the option to increase their level of risk annually during the agreement period.

Response: In the December 2014 proposed rule we did not propose or seek comment on modifications to the design of Track 1 to increase the opportunity for reward under this model, such as revisions to the Track 1 MSR methodology. Although we appreciate commenters' thoughtful recommendations for improving the rewards under Track 1, we consider these suggestions beyond the scope of this final rule and we decline at this time to adopt commenters'

recommendations. Further, we continue to believe it is important to maintain the MSR under the one-sided model to protect against paying shared savings based on changes in cost that result from normal variation in expenditures. We also remain committed to the belief that ACOs who accept financial responsibility for the care of beneficiaries have the greatest beneficial effects for the Medicare program and its beneficiaries. Keeping with the initial design of the program, the differences between the tracks encourage ACOs to transition from one-sided risk to two-sided risk by providing greater reward to those who accept greater risk. We believe that adjusting the sharing rate and the other aspects of the Track 1 financial model to match more closely, or exactly, the up-side available under the two-sided risk tracks would undermine our effort to encourage ACOs to transition to performance-based risk.

We appreciate commenters' thoughtful considerations on how to encourage ACOs to transition to performance-based risk. As indicated in other sections of this final rule, we are finalizing certain modifications to program policies to encourage ACOs to enter performance-based risk arrangements. These modifications respond to commenters' recommendations for improving the financial incentives under the program and allowing ACOs a range of options with respect to features of the tracks they may select from (for example, prospective versus retrospective assignment methodology and level of risk in relation to opportunity for reward). Although we are not adopting the additional suggestions recommended by some commenters in this rule, we will further consider these suggestions and may propose additional revisions to encourage ACOs to enter performance-based risk arrangements through future notice and comment rulemaking.

b. Transition From the One-Sided to Two-Sided Model

(1) Second Agreement Period Under Track 1

We considered several options to better balance both our intent to encourage continued participation by ACOs that entered the program under the one-sided model but that are not ready to accept performance-based risk after 3 years of program participation with our concern that allowing a shared savings only option will discourage ACOs capable of taking risk from moving to a two-sided model. We considered the following options:

- Revising the regulations to allow ACOs that enter the program under the one-sided model to continue participation in Track 1 for more than one agreement period.

- Extending the initial 3-year agreement period for an additional 2 years for ACOs that enter the program under Track 1, but that do not believe that they are ready to advance to a risk-based track.

- Allowing ACOs to continue participation in Track 1 for more than one agreement period, but revising the one-sided model to decrease the financial attractiveness of the model, so as to encourage ACOs ready to accept performance-based risk to transition to a two-sided model. Among these options, we expressed our belief that the third option offered a good balance of encouraging continued participation in addition to encouraging progression along the on-ramp to performance-based risk. Therefore, we proposed to remove the requirement at § 425.600(b) that ACOs that enter the program under Track 1 (one-sided model) must transition to Track 2 (two-sided model) after one agreement period, if they wish to continue participating in the Shared Savings Program. Instead, we proposed to revise the regulation to permit ACOs that have completed a 3-year agreement under Track 1 to enter into one additional 3-year agreement under Track 1.

Comment: Most commenters generally supported policies that would allow Track 1 ACOs to continue in the program under the one-sided model, with many commenters addressing the specifics of the proposed policies and offering alternative suggestions.

Most commenters generally and strongly supported policies that would permit ACOs to participate in the Shared Savings Program under a one-sided model for a longer period of time, indicating that the transition to performance-based risk under the current rule is too soon and steep for most ACOs. A commenter indicated that the progression to risk outlined in the current rule was too aggressive in light of the challenges ACOs and CMS faced during the initial program startup period.

The majority of commenters strongly supported our specific proposal to permit one additional agreement period under Track 1. Generally commenters agreed with CMS' concern about the transition to risk posed by the existing rule, which could require organizations to choose between taking on more risk and exiting the program after one agreement period. Commenters pointed to a variety of benefits from allowing

ACOs additional time under the one-sided model:

- Allows ACOs more than 3 years to mature and develop the necessary infrastructure and capabilities, in which they have invested significant time and capital, to meet the program's goals, including: testing patient-centered approaches, providing care management services, implementation of electronic medical records (EMRs), and performing data analytics and risk assessment.

- Affords ACOs additional time needed to develop the infrastructure and experience needed to assume greater risk. Comments explained that ACOs need more than 3 years to develop the necessary infrastructure and competencies to effectively manage down-side risk. A commenter explained that past experience from the PGP demonstration and the Pioneer ACO Model indicates that providers need more than 3 years to produce meaningful savings and to develop sufficient skills to manage downside risk. Indeed, several commenters explained that some Track 1 ACOs may not be risk averse, but rather are reluctant to enter a performance-based risk arrangement given concerns, such as the financial viability of shared savings for ACOs in low-cost regions, and the risk of program participation posed by the significant and incremental operational costs for ACOs.

- Encourages continued participation by existing ACOs and makes the program more attractive to prospective ACOs. Commenters emphasized the importance of giving ACOs the opportunity to generate savings to further fund their operations without risk of accountability for losses, for the success of ACOs and the program. Commenters indicated this issue may be especially relevant for smaller organizations and those less experienced with care redesign processes and with performance-based risk, existing low-cost ACOs (which may need additional time to further their care management efforts to achieve additional savings), and ACOs led by academic medical centers (which tend to treat sicker and more complex patient populations than other providers). A commenter indicated the importance of continued participation by Advance Payment Model ACOs under Track 1, in order for CMS to recoup pre-paid shared savings from these organizations.

Some commenters opposed the proposal to allow ACOs to continue under the program for only one additional agreement period, favoring a slower transition to risk than was proposed. These commenters suggested that CMS offer multiple agreement

periods under Track 1 (for instance two full agreement periods and part of a third agreement period). Others recommended alternatives such as permitting select types of ACOs, such as rural- or physician-only ACOs, or existing low-cost ACOs, to continue under Track 1 for more than two agreement periods. A commenter suggested allowing ACOs to remain in Track 1 as long as they meet program requirements or until additional risk-bearing payment models, such as full capitation, risk-adjusted capitations, and prepayment, are available under the program or both. A commenter suggested that any exemptions for ACOs from the requirement to transition to two-sided risk arrangements should be limited to those states where state law does not allow for contracts between payer and provider that incorporate downside risk.

On the other hand, a few commenters were opposed to this proposal, stating that ACOs should be capable of moving to risk in a more aggressive timeframe, and that eliminating the requirement to move to risk after the first agreement period sends the wrong signal. Several commenters pointed to private sector ACO initiatives to illustrate that organizations can be ready for two-sided risk within a few years. These commenters urged CMS to hasten the transition to performance-based risk by Track 1 ACOs, for instance by allowing them less than a full second agreement period under Track 1, or no additional time under Track 1.

More generally, some commenters stated their agreement with CMS' emphasis on the importance of two-sided risk as a driver of more meaningful change. A commenter explained: two-sided risk creates a greater onus of accountability, and ultimately encourages providers to respond to what patients need. It also injects greater momentum into the pace of change in the development of the care processes that are needed to achieve success in a risk environment. If there is no risk, the system may reward providers that are ACOs in name only.

However, in the drive to move ACOs to the two-sided model, other commenters urged CMS not to lose sight of the benefits of having robust participation under the one-sided model. Several commenters urged CMS not to overlook or withdraw its support from Track 1 ACOs, for instance pointing out that the Track 1 serves as the primary model for the vast majority of existing ACOs, and urging CMS to recognize the value that Track 1 brings to Medicare in capturing savings and serving as a vehicle for advancing new

models of care that create value for Medicare beneficiaries. A commenter was critical of the overall policy direction of the proposed rule, to encourage ACOs to move to performance-based risk, explaining that this was unjustified given that CMS is receiving substantial savings from ACOs participating under the one-sided model. A commenter cautioned CMS that the goal to incentivize ACOs to move into two-sided risk models should not overshadow the underlying statutory intent of the Shared Savings Program, which is to drive improvements in patient care and reductions in overall health care costs. A commenter noted the need for CMS to support Track 1 ACOs until they evolve into organizations that can better coordinate care of beneficiaries and take on additional risk. Another commenter noted that the perceived rush to move all ACOs to two-sided risk models undermines other CMS pilot programs, such as the Bundled Payments for Care Improvement (BPCI) and the Pioneer ACO Model.

Response: We are finalizing our proposal to permit ACOs to participate in an additional 3-year agreement period under Track 1, for a total of two agreement periods under the one-sided model. We believe giving ACOs one additional agreement under Track 1 is responsive to the many comments we received that some ACOs require additional time before moving to a two-sided risk arrangement. In particular, we are persuaded by commenters' urging of the need for ACOs to gain additional experience under accountable care models before transitioning to performance-based risk, as well as the benefits to CMS and Medicare beneficiaries of encouraging continued participation by ACOs—including those who received Advanced Payments from the Innovation Center—in light of the alternative that these ACOs would terminate their participation altogether. We continue to believe that ACOs who accept responsibility for the quality and cost of the care furnished to beneficiaries have the greatest positive effect on the Medicare program and its beneficiaries. We believe that allowing ACOs a second 3-year agreement period under the one-sided model strikes a reasonable balance between permitting ACOs additional time under Track 1 and maintaining a clear timeframe for when ACOs must transition to performance-based risk. We disagree with commenters' suggestions to allow select ACOs (based on their geographic location, historical cost or provider composition) to remain under the one-

sided model indefinitely. We believe such a policy design would encourage ACOs to languish under the one-sided model. We also disagree with commenters who suggest that ACOs should be pushed to transition to performance-based risk in a shorter time, given the volume of concerns we heard as we developed the proposal to allow ACOs additional time under the one-sided model and from comments received in response to the proposed rule. We believe that a requirement for ACOs to immediately transition to risk after the conclusion of their first agreement period, or before the end of their second agreement period could result in significant attrition from the program, particularly by ACOs that are newly formed or underfunded.

Comment: Some commenters identified the most immediate challenges faced by ACOs with 2012 and 2013 agreement start dates who are considering renewing their agreement period for the 2016 performance year. For example, a commenter indicated that ACOs may lack the performance data needed at the time of agreement renewal (based on 2 performance years) to make an informed decision between a second agreement period under Track 1 or entering a performance-based risk arrangement. In addition, some commenters further pointed out they could have a relatively short period in which to make this decision given the short timeline CMS faces in issuing a final rule that would be effective for the 2016 performance year and implementing the finalized policies. In light of these factors, some commenters recommended that CMS allow current ACOs the option to extend their current contracts by 1, 2 or 3 years, or if they choose, to enter into a new agreement period under the two-sided model. These commenters explained that extension of the ACOs' existing agreements would allow certain ACOs more time to determine their readiness to change tracks and assume risk, while those that are prepared to accept new contract terms and shift to greater risk at this time could do so.

Some other commenters recommended instead that CMS extend the current ACO participation agreement from its current 3 years to a 5-year agreement, for all tracks, including not only the initial agreement, but all subsequent agreements. These commenters explained that this would make the program more attractive by increasing program stability and providing ACOs with the necessary time to achieve the desired quality and financial outcomes. However, a commenter expressed concern that

rebasings every 5 years (as opposed to rebasing with each 3-year agreement) may not be authorized under section 1899(d) of the Act.

Response: Section 1899(d)(1)(B)(ii) of the Act specifies the benchmark shall be reset at the start of each agreement period, while section 1899(b)(2)(B) specifies the ACO shall enter into an agreement to participate in the program for not less than a 3-year period. While we have the authority under section 1899(b) of the Act to establish agreements for periods longer than a term of three years, we decline to take commenters' suggestions regarding extending the first agreement period for ACOs. We believe it is appropriate to maintain a 3-year agreement period to provide continuity with the design of the program finalized with the November 2011 final rule. Furthermore, we do not believe an extension of ACO's first agreement period is necessary, particularly to address the situation of ACOs whose agreements conclude December 31, 2015, given the modifications to the program's current rules that we are making in this final rule. For one, we are finalizing our proposal to permit ACOs to participate in an additional agreement period under Track 1. This change should alleviate concerns of commenters who favored extending the agreement period to make the program more attractive to Track 1 ACOs, particularly those who need additional time in Track 1 to become experienced with the accountable care model before transitioning to performance-based risk. Second, as explained in greater detail elsewhere in this final rule, we are modifying the rebasing methodology to make continued participation in the program more attractive to ACOs, particularly by equally weighting the benchmark years and accounting for savings generated under the ACO's prior agreement period. These modifications address commenters' concerns regarding the need for extended agreement periods to provide greater stability to ACO benchmarks. Further, we recognize that the longer the agreement period, the greater an ACO's chance to build on the success or continue the failure of its current agreement. Therefore we believe rebasing every 3 years, at the start of each agreement period, is important to protect both the Trust Funds and ACOs.

FINAL ACTION: We are finalizing our proposal to remove the requirement at § 425.600(b) that ACOs that enter the program under Track 1 (one-sided model) must transition to Track 2 (two-sided model) after one agreement period if they wish to continue participating in the Shared Savings Program. We are

revising the regulation to permit ACOs that have completed a 3-year agreement under Track 1 to enter into one additional 3-year agreement under Track 1. We have also made some minor revisions to the proposed language at § 425.600(b) to further clarify that ACOs may operate under the one-sided model for a maximum of two agreement periods.

(2) Eligibility Criteria for Continued Participation in Track 1

In section II.C.3. of this final rule, we discuss criteria for determining whether to allow ACOs that are currently participating in the program to renew their participation agreements for subsequent agreement periods. We proposed to make the option of participating in Track 1 for a second agreement period available to only those Track 1 ACOs that: (1) Meet the criteria established for ACOs seeking to renew their agreements (as discussed in section II.C.3. of this final rule, including demonstrating to CMS that they met the quality performance standard during at least 1 of the first 2 years of the previous agreement period); and (2) did not generate losses in excess of the negative MSR in at least 1 of the first 2 performance years of the previous agreement period. We explained that if the ACO's financial performance results in expenditures in excess of the negative MSR in only 1 of the first 2 performance years, then we would accept the ACO's request to renew its participation agreement under the one-sided model, provided all other requirements for renewal were satisfied. Through this proposed policy we aimed to encourage the continued participation of ACOs that are successful and have the potential to move toward accepting greater responsibility for the care of their beneficiaries. Further, we explained that the proposed policy would prevent consistently poor performers from being able to seamlessly continue in program participation under the one-sided model while permitting some leeway for ACOs that are new to the program and may have had some difficulty in cost or quality performance in 1 of the first 2 performance years. We further explained that these additional eligibility criteria would serve as an important safeguard to reduce the potential for ACOs to participate in the program for reasons other than a commitment to improving the value of health care services. We also recognized that because our assessment would be based on only 2 years of data, we would not have a complete picture of the ACO's performance during the

agreement period. That is, an ACO may financially perform very poorly, exceeding the negative MSR in its first and second performance years, but demonstrate a trend in a direction that could ultimately lead to better performance in the third year. Under our proposal this ACO would not be permitted to renew its agreement under Track 1 for a second agreement period. However, we acknowledged that an argument could be made that this ACO simply needed the additional time under a one-sided model to gain experience and start improving. Therefore, we sought comment on whether we should also consider the direction the ACO's performance is trending when determining whether to permit renewal of an ACO's participation agreement under Track 1. We also sought comment on whether other options for such ACOs, short of refusing their participation in a second agreement period under Track 1, would better serve program goals. We noted that such ACOs would not be precluded from renewing their participation agreement in order to participate under a two-sided risk track, consistent with § 425.600(c). We also emphasized that in addition to meeting the specific criteria to be eligible to continue in Track 1, the ACO must also demonstrate that it meets the requirements to renew its agreement under proposed § 425.224, which would include the requirement that the ACO establish that it is in compliance with the eligibility and other requirements of the Shared Savings Program. While the eligibility criteria for renewing ACOs are discussed in detail in section II.C.3. of this final rule, the following discussion is limited only to the additional financial performance criterion proposed for determining the eligibility of Track 1 ACOs to continue under the one-sided model for a second agreement period.

Comment: Several commenters agreed with the proposed criteria for evaluating whether an ACO could continue under Track 1, for example indicating that the proposed criteria would reasonably hold ACOs accountable for noticeable improvement in their first agreement period. A commenter explained that it is important that failing organizations not continue "free-riding" the benefits of the program without showing clear signs of improving quality and controlling health care costs. Several other commenters also expressed direct support for the financial performance criterion as proposed.

However, several others recommended more stringent requirements than those we proposed,

for instance suggesting CMS terminate the following categories of ACOs from the program:

- ACOs who do not demonstrate year-to-year improvements in controlling costs and improving quality.
- ACOs who failed to meet their benchmark under their first agreement period (or allow these ACOs to participate for a second agreement period only under a reduced sharing rate).

On the other hand, many commenters were opposed to using an ACO's prior financial performance, as proposed, to determine whether it should be permitted to continue under Track 1. Commenters offered a number of reasons for opposing a requirement that ACOs must not have generated losses in excess of their negative MSR in at least 1 of the first 2 performance years to be eligible to continue in Track 1:

- The policy may disadvantage certain ACOs that need more time to fully implement strategies in care management that consistently yield savings, such as newly formed, smaller and rural ACOs, and those with certain provider compositions (such as those that include teaching hospital participants).
- The policy may discourage providers from participating in ACOs because it sends a signal that CMS will "pull the plug" on underperforming ACOs, and seems not to recognize the significant start-up costs and learning curve to establish a successful ACO.
- It may be premature to judge an ACO's ability to perform on data from only 2 years of program participation, particularly as some ACOs have faced a steep learning curve.

Several commenters pointed to publicly available performance results in explaining that variation in generating savings and losses relates more to an ACO's benchmark per capita spending than to the ACO's number of assigned beneficiaries (and therefore its MSR under the one-sided model). In light of this information, commenters suggested that CMS reconsider the proposed financial performance requirement for continued participation in Track 1.

Some commenters requested greater leniency in determining whether ACOs can continue participating in Track 1 based on their past financial performance and suggested various alternatives to the proposed criteria which include the following:

- Removing the financial performance criterion altogether from the determination of whether an ACO is eligible to renew under Track 1, with some commenters suggesting CMS focus

more on ACO quality performance in determining their eligibility to renew their agreements.

- A case-by-case assessment of each ACO not meeting the criterion or a reconsideration process, or both, so that CMS can review any compelling reasons why the organization generated losses outside its negative MSR in its first 2 years and consider any mitigating factors (for example, patterns of performance improvement or changes in ACO composition).

- Consideration of the ACO's performance trend over the first 2 years, and if the ACO's financial or quality data showed improvement from the first to the second year, then it would be permitted to renew under Track 1, or permitting ACOs to continue in Track 1 under probationary status for 1 or 2 years to allow them time to demonstrate a change in trends.

- Permitting ACOs that exhibit bona fide efforts to pursue the program's goals to continue under Track 1.

A commenter indicated that entities should only be permitted the opportunity to renew under the one-sided model for one additional 3-year agreement, and entities that are unable to demonstrate adequate performance within 6 years should not be permitted to remain in the Shared Savings Program.

Several comments seemed to reflect commenters' misunderstanding of the proposed policy, interpreting it to mean that an ACO who either failed to satisfy the quality performance requirements in one of its first 2 performance years, or generated losses in excess of its negative MSR in one of its first 2 performance years would be ineligible to continue in Track 1 for a second agreement period. Another commenter seems not to have understood the proposed policy, believing CMS indicated that only ACOs with losses outside their negative MSR would be eligible to continue in Track 1 for a second agreement period.

Response: As discussed in section II.C.3. of this final rule, we are finalizing general criteria that will apply to all renewing ACOs, including the requirement that an ACO meet the quality performance standard during at least 1 of the first 2 years of its previous agreement period. We are persuaded by commenters' concerns that application of the additional proposed financial performance criterion for continued participation in Track 1 may come too early for ACOs who initially struggle to demonstrate cost savings in their first years in the program. Therefore, we are modifying our proposed criteria for an ACO to qualify for an additional agreement period under Track 1. We are

not finalizing an additional renewal criterion for ACOs seeking to renew for a second agreement period under Track 1 that would consider the ACO's financial performance during its first 2 performance years in its prior agreement period. We believe that the general criteria that would apply to all renewing ACOs (see section II.C.3. of this final rule) are sufficient to address program integrity and program compliance concerns that failing organizations or those lacking a bona fide interest in the program would be allowed to continue their participation. Further, we believe our authority to monitor ACOs (§§ 425.316) allows us to take action to address ACOs who are outliers on financial performance by placing poorly performing ACOs on a special monitoring plan. Furthermore, if our monitoring reveals that the ACO is out of compliance with any of the requirements of the Shared Savings Program, we may request a corrective action plan and, if the required corrective action is not taken or satisfactorily implemented, we may terminate the ACO's participation in the program.

Comment: Several commenters made suggestions that CMS focus on establishing criteria for determining an ACO's readiness to transition to performance-based risk. Generally, some comments suggested that ACOs should be encouraged to adopt two-sided risk payment models as soon as they have the capacity to do so. Commenters offered a variety of suggestions on how CMS could determine an ACO's readiness to accept performance-based risk. A commenter suggested Track 1 ACOs whose performance year expenditures are lower than their benchmarks should move into the two-sided model. A commenter suggested requiring ACOs to achieve shared savings under Track 1 before being permitted to move to a two-sided model; another commenter suggested that ACOs transition to the two-sided model once they demonstrate success in the program by earning a shared savings payment in 2 consecutive performance years. A commenter suggested looking at the ACO's performance trends and whether it is accredited by NCQA or URAC in determining its readiness to transition to performance-based risk, and, if not, allowing an annual renewal process for up to 3 additional years under Track 1 beyond the first agreement period. A few commenters suggested that ACOs with a certain composition of ACO participants be required to transition to two-sided risk sooner, for instance suggesting that

hospital/health system-led or sponsored ACOs should be pushed towards two-sided risk based on the belief that these ACOs are more entrenched in volume-based (as opposed to value-based) incentives. A commenter suggested that an ACO's risk sharing should vary based on its data sharing capabilities in relation to the availability of data sharing infrastructure in the state where it is located. According to this commenter, this approach would recognize the disparities in states' capabilities to share data through health information exchanges, and the higher costs for ACOs to develop data sharing infrastructure in states without robust, preexisting data sharing infrastructure.

More generally, a few commenters recommended allowing ACOs to remain in Track 1 until they can demonstrate readiness to accept performance-based risk. A commenter recommended that CMS continue to explore additional ways to provide Track 1 ACOs with a glide path to two-sided risk and articulate a defined point at which Track 1 ACOs must move into Track 2 or 3.

Response: Under the general framework of the Shared Savings Program, as modified by this final rule, ACOs participating under the one-sided model will be required to transition to the two-sided model or terminate their participation after the conclusion of their second agreement period under Track 1. As previously discussed, this policy balances the need for ACOs to gain more experience in the program under the one-sided model with the importance of ACOs transitioning to performance-based risk. We appreciate the suggestions around establishing criteria for determining ACO readiness to accept risk. However, we consider these comments beyond the scope of the proposals and other issues on which we sought comment in the December 2014 proposed rule, and decline at this time to implement additional requirements for determining an ACO's readiness to enter performance-based risk arrangements. As comments discussed elsewhere in this final rule indicate, the decision to enter performance-based risk is highly specific to each organization, and its perceived readiness to bear performance-based risk in relation to various other factors including (among others) its provider composition and historical cost performance and financial trends, assigned beneficiary population, and the benchmarking and shared savings/losses methodology under the Shared Savings Program.

FINAL ACTION: The general criteria described in section II.C.3. of this final rule apply to all renewing ACOs,

including Track 1 ACOs applying for a second agreement period under the one-sided model. Under § 425.224(b), CMS will evaluate an ACO's participation agreement renewal based on all of the following factors:

- Whether the ACO satisfies the criteria for operating under the selected risk model.
- The ACO's history of compliance with the requirements of the Shared Savings Program.
- Whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program, including the ability to repay losses, if applicable.
- Whether the ACO met the quality performance standards during at least 1 of the first 2 years of the previous agreement period.
- For an ACO under a two-sided model, whether the ACO has repaid losses owed to the program that it generated during the first 2 years of the previous agreement period.
- The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.304(b)).

We are not finalizing any additional financial performance criteria for determining the eligibility for Track 1 ACOs to continue under the one-sided model for a second agreement period. We have modified the proposed revisions to § 425.600(b) to reflect this final policy. Additionally we are making conforming changes to § 425.600(c). This provision currently specifies that an ACO with net losses in its initial agreement period that reapplies to participate under the program must identify in its application the cause(s) for the net loss and what safeguards are in place to enable the ACO to potentially achieve savings in the next agreement period. Specifically, we are revising the provision to apply to ACOs seeking to renew their participation agreements for a second or subsequent agreement period.

(3) Maximum Sharing Rate for ACOs in a Second Agreement Period Under Track 1

As part of our proposal to allow ACOs to participate in a second agreement period under the one-sided model, we proposed to reduce the sharing rate by 10 percentage points for ACOs in a second agreement period under Track 1 to make staying in the one-sided model less attractive than moving forward along the risk continuum. As a result, the maximum sharing rate for an ACO in a second agreement period under Track 1 would be 40 percent.

Accordingly, in addition to our proposed change to § 425.600(b) to allow ACOs to participate under Track 1 for a second agreement period, we proposed to modify § 425.604(d) to provide that the maximum sharing rate during a second agreement period under Track 1 would be 40 percent.

We sought comment on this proposal. In particular, we requested input on whether a 40 percent sharing rate in a second agreement period under the one-sided model is sufficient to incentivize an ACO that may need more time to prepare to take on two-sided performance-based risk while also encouraging ACOs that are ready to take on performance-based risk to choose to continue participation in the Shared Savings Program under a two-sided model.

We also considered other variations and options for allowing ACOs additional time in the one-sided model. For example, we considered allowing ACOs to continue under Track 1 for a second agreement period without any changes to the sharing rate (that is, retaining the 50 percent sharing rate in the second agreement period). However, we expressed our concern that if ACOs are able to continue to receive up to 50 percent of savings in a second agreement period there may be insufficient incentive for many ACOs that may be ready to take on two-sided risk to move to a track with two-sided risk after their first agreement period. We specifically sought comments on the other options we considered, including extending an ACO's Track 1 agreement period for an additional 2-years rather than permitting two 3-year agreement periods under Track 1, permitting ACOs to participate in a second agreement period under Track 1 with no change to the sharing rate, and offering multiple agreement periods under Track 1 while reducing the sharing rate by 10 percentage points for each subsequent agreement.

Comment: Some commenters, including MedPAC, were in favor of reducing the sharing rate for ACOs in a second agreement period under Track 1. Several commenters noted the importance of moving ACOs to performance-based risk for driving meaningful changes by providers in health care quality and spending, and a commenter recognized that not all ACOs will be able to make this transition. In this commenter's view, CMS should not be focused on maximizing the number of ACOs in the program, rather it should be encouraging ACOs with robust ability to improve quality and control spending growth to be in the program and to reward them appropriately. Several

commenters indicated that the proposed reduction of the sharing rate by 10 percentage points in the second agreement period strikes a reasonable balance between allowing promising ACOs to continue for a limited time without bearing risk and encouraging ACOs to transition to two-sided risk. Another commenter explained that the lower sharing rate would provide an incentive to entities that may be on the cusp of considering moving to a two-sided risk model. Several suggested dropping the rate to 45 percent for ACOs continuing under the one-sided model after their first agreement period in combination with increasing the sharing rate (for example, by at least 5 percentage points) under the two-sided model to serve as an incentive for ACOs to transition to performance-based risk. At the same time, several other commenters recommended dropping the sharing rate under the one-sided model even further, for example to 20 percent, 25 percent or 30 percent under the second agreement period, or making a 5 percentage point reduction for each year under the second agreement period. These commenters expressed concern that the proposed 10 percentage point reduction in the sharing rate for ACOs that continue in Track 1 may not be sufficient to encourage ACOs to more quickly accept performance-based risk.

However, a majority of the commenters were strongly opposed to reducing the sharing rate under a subsequent Track 1 agreement. These commenters cautioned that such a policy could have adverse effects on program participation, suggesting the reduction in sharing rate would be a significant disincentive for ACOs to continue in the program and may discourage ACOs from forming. In particular, ACOs may choose to leave the program, or not enter the program at all, if they determine they are not prepared to transition to performance-based risk tracks, which offer higher sharing rates, and the proposed 40 percent sharing rate under Track 1 is insufficient to justify the cost and effort required to reach and maintain the high level of performance needed to achieve success. Others stated their belief that reducing the sharing rate under the one-sided model is merely punitive. Commenters provided a variety of reasons why a reduction in sharing rate disadvantages ACOs and the program. Many pointed to the financial risk of ACO formation and participation in the program under the one-sided model due to the significant upfront investments necessary for ACO formation and ongoing operational costs to support

infrastructure (such as IT solutions) and process development, staffing, population management, care coordination, quality reporting, and patient education. Some explained that the existing sharing rate of 50 percent is too low, and a further reduction in the sharing rate would ratchet down the potential for ACOs to realize return on investment, which is the key for some organizations to continue funding their operations. Some commenters pointed to the phase-in of pay for performance for quality measures as a factor that will further reduce the sharing rate for Track 1 ACOs. Others pointed to the MSR as already providing an additional hurdle for Track 1 ACOs to cross before they may share in savings they generate. Others pointed to the program's first year financial performance results and the limited number of ACOs that shared in savings, indicating it is too soon to reduce the sharing rate since so few ACOs have begun to see any return on investment. Another commenter pointed out that a reduced sharing rate would impair ACOs' ability to appropriately reward participating providers. Taken together, commenters explained their belief that this level of return on investment is not sustainable for ACOs and could result in ACOs leaving the program. A few commenters noted the particular importance of maintaining the sharing rate for small, provider-based and rural ACOs. A commenter suggested sustaining the sharing rate at 50 percent under the one-sided model could encourage small, rural ACOs to enter and remain in the program, explaining that these types of entities may face a steeper learning curve in developing the capacity to meet the program's goals (for instance needing more time to fully implement strategies in care management that consistently yield savings and developing collaborations across providers to enable effective care management), and require additional capital and human resources to succeed. Several commenters explained that a reduced sharing rate under the one-sided model does not improve the attractiveness of the two-sided model. Others explained that maintaining the current sharing rate could provide ACOs with the funds needed to support the ACO and to prepare for managing increased performance-based risk.

In the alternative, some commenters recommended the following different approaches that would maintain the Track 1 sharing rate at 50 percent, slow the reduction of the sharing rate, or increase the sharing rate for ACOs that

continue under Track 1 after their first agreement period:

- Increase the sharing rate, for example, to over 80 percent.
- Allow ACOs to continue in Track 1 indefinitely with no reduction in sharing rate.
- Allow ACOs to continue in Track 1 for more than 2 agreement periods with a continued reduction in sharing rate (for example, a 10 percentage point decrease) for each subsequent agreement. Several commenters suggested a slower phase-in of the reduction of the sharing rate, for example by reducing the sharing rate below 50 percent starting in the third agreement period.
- Allow Track 1 ACOs the opportunity to extend their initial 3 year agreement by 2 or 3 additional years, and to maintain the 50 percent sharing rate during these additional years.
- Decreasing the sharing rate only for select ACOs as a means of encouraging these ACOs to move to the two-sided model while providing sufficient incentive for ACOs with less success to continue to innovate in a subsequent agreement period under Track 1. For instance, decreasing the sharing rate for ACOs that demonstrated shared savings in their first agreement period, or decreasing the sharing rate for higher-cost ACOs (or requiring these ACOs to accept performance-based risk) while increasing the sharing rate for lower-cost ACOs.

A few commenters suggested that certain types of ACOs should be exempt from the reduction in sharing rate, such as rural ACOs, and ACOs comprised largely of practicing physicians or primary care physicians (as opposed to ACOs that include a hospital or health system as an ACO participant).

Response: We were influenced by the comments indicating that a reduced sharing rate under the one-sided model does not necessarily increase the attractiveness of the two-sided model, but rather could impede the progression to risk by ACOs needing additional experience with the accountable care model. Specifically, we are persuaded by comments suggesting that maintaining the sharing rate at a maximum of 50 percent for Track 1 may result in payments to ACOs that in turn can be used by ACOs to prepare their infrastructure and financial reserves for transitioning to performance-based risk. We further believe this policy helps address concerns of commenters about the need for ACOs to achieve a return on investment through shared savings, and in particular, could encourage continued participation by ACOs who have not yet been eligible for a

performance payment by the time they must determine whether to continue in the program for a second agreement period. Further, since we are only permitting one additional agreement period under the one-sided model, as opposed to multiple additional agreement periods, we believe it is reasonable to sustain the maximum sharing rate at 50 percent. In light of this determination, we decline to accept the suggestions by commenters to further reduce the sharing rate for ACOs who continue under Track 1 (to lower than 40 percent). Given our interest in ACOs progressing to performance-based risk, we decline to accept the recommendations to more slowly transition ACOs to performance-based risk arrangements, such as the suggestions to allow multiple agreement periods under Track 1 with the same or a progressively decreasing sharing rate. We also decline to select certain ACOs for eligibility for a reduced sharing rate, based on past performance, composition or geography, because we believe the previously noted considerations that support maintaining the sharing rate at 50 percent are applicable to ACOs of varying forms and locations. At the same time, we believe that decreasing the sharing rate for ACOs who remain under the one-sided model would provide little if no incentive for ACOs to eventually transition to performance-based risk, and could result in ACOs languishing under the one-sided model. Therefore, we are finalizing a policy that would offer continuation of the 50 percent sharing rate to ACOs participating in a second agreement under Track 1.

FINAL ACTION: We are not finalizing our proposed amendment to section 425.604(d) to reduce the maximum sharing rate during an ACO's second agreement period under Track 1. Therefore, an ACO participating under Track 1 for a second agreement period that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings, as determined on the basis of its quality performance, as currently specified under § 425.604(d).

(4) Eligibility for Continued Participation in Track 1 by Previously Terminated ACOs

In light of our proposed revisions to § 425.600 to permit an ACO to participate under Track 1 for a second agreement period, we proposed conforming changes to § 425.222(c) to permit previously terminated Track 1 ACOs to reapply under the one-sided model. We proposed that, consistent

with our existing policy under § 425.222(c), an ACO whose agreement was terminated less than half way through the term of its participation agreement under Track 1 would be permitted to reapply to the one-sided model as if it were applying for its first agreement period. If the ACO were accepted to reenter the program, the maximum sharing rate would be 50 percent. However, in the case of an ACO that was terminated more than half way through its initial agreement under the one-sided model, we proposed to revise § 425.222(c) to permit this ACO to reapply for participation under the one-sided model, but to provide that the ACO would be treated as if it were applying for a second agreement period under Track 1. Thus, if the ACO were approved to participate in the program again, the reduced sharing rate of 40 percent would apply. An ACO whose prior agreement under Track 2 was terminated would still be precluded from applying to participate under Track 1. We sought comment on these proposals.

We further noted in December 2014 proposed rule that the option to participate under the one-sided model agreement in a subsequent agreement period is only available to ACOs that have completed or are in the process of completing an agreement under the one-sided model. That is, we would not permit an ACO that had participated under a two-sided model to subsequently participate under a one-sided model.

Comment: We received very few comments on these proposals. A commenter supported the proposal to allow previously terminated ACOs to reapply to Track 1 if they can still meet the necessary eligibility requirements and demonstrate the capability to meet program financial and quality targets.

Several commenters disagreed with the policy that an ACO that was previously terminated from Track 2 would not be allowed to reapply to Track 1. These commenters explained that it may be more prudent for these organizations to reapply for Track 1 and then move to Track 2 when they are ready. A commenter specifically suggested that CMS should allow any ACO, regardless of what track it entered the program under and when it was terminated, to reapply for Track 1 at a 50 percent sharing rate. A commenter suggested that an ACO that was terminated from Track 2 should be allowed to enter into Track 1; however, under these circumstances the ACO should be required, as part of its application, to provide detailed plans

for correcting the deficiencies noted under the prior agreement.

A commenter expressed support for an existing program policy specified at § 425.222(a) of the regulations, under which an ACO that has been terminated from the Shared Savings Program under §§ 425.218 or 425.220 may participate in the Shared Savings Program again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated. The commenter explained that it is important to recognize that not all ACOs are immediately able to assume the full responsibility of shared savings. The onboarding process of becoming an ACO and developing the capabilities to achieve shared savings takes some organizations longer than anticipated, especially given some of the uncertainties of a new program. The commenter recommended that those ACOs that re-enroll in the program should be required to demonstrate improvement in the capabilities necessary to succeed under a shared savings model. The commenter recommended that CMS revisit at a later time the issue of whether and under what conditions previously terminated ACOs should be allowed to reapply.

Response: Under our final policy to allow Track 1 ACOs who continue under the one-sided model for a second agreement period to be eligible for a maximum sharing rate of 50 percent based on quality performance, the issue of when to apply a reduced sharing rate for previously terminated ACOs who reapply to Track 1 is superseded. However, we are finalizing our proposed approach for determining whether an ACO previously terminated from Track 1 is re-entering the program under its first or second agreement period under Track 1, specifically an ACO whose agreement was terminated—

- Less than half way through its first agreement under the one-sided model will be permitted to reapply to the one-sided model as if it were applying for its first agreement period; or
- More than half way through its first agreement under the one-sided model will be permitted to reapply to the one-sided model and would be treated as if it were applying for a second agreement period under Track 1.

Since we are finalizing a policy under which ACOs may continue to participate in the one-sided model for a second agreement period, we believe it is important to clarify the choice of financial models for ACOs whose participation is terminated under their second agreement period and reapply to participate in the program. In

addressing this issue, we believe it is important to align with the approach established by the original policy: To give an ACO whose participation was terminated before completing half of its agreement period the opportunity to reapply to enter the financial model it was participating under at the time of termination. Specifically:

- An ACO whose agreement was terminated less than half way through its second agreement period under the one-sided model will be permitted to reapply to the one-sided model and would be treated as if it were applying for a second agreement period under Track 1.
- An ACO whose agreement was terminated more than half way through its second agreement under the one-sided model will only be permitted to reapply for participation under the two-sided model.

We are revising the regulation at § 425.222(c) to reflect this clarification.

We will not at this time to modify our current policy that prohibits an ACO whose prior agreement under Track 2 was terminated from applying to participate under Track 1. Commenters presented reasons for why ACOs who terminate from the two-sided model should be allowed to reenter the program under the one-sided model. However, in light of our decision to extend participation under Track 1 for a second agreement period, we believe it is especially important to establish policies to support an earnest transition to performance-based risk by Track 1 ACOs. Should we finalize a policy that allows terminated two-sided model ACOs to reapply to Track 1, we are concerned this would create an opportunity for Track 1 ACOs to enter the two-sided model and quickly terminate in an effort to reset the clock on the participation in the one-sided model.

Further, we appreciate commenter's suggestions about the need for terminated ACOs reapplying to the program to demonstrate their capacity to achieve program goals. As we established in the 2011 final rule, a terminated ACO reapplying to the program must describe the reason for termination of its initial agreement and explain what safeguards are now in place to enable the prospective ACO to participate in the program for the full term of its participation agreement. We continue to believe it is an important beneficiary and program protection to limit participation in the program to providers and suppliers who are dedicated to the goals of the program.

We appreciate the commenters' support for the existing policy under

which a previously terminated ACO may participate in the Shared Savings Program again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated. As we explained in the 2011 final rule (76 FR 67961), we continue to believe that in order to ensure protection for beneficiaries and the program, ACOs should not be allowed to re-enter the Shared Savings Program before the conclusion of their initial agreement period.

FINAL ACTION: We are finalizing our proposal to permit previously terminated Track 1 ACOs to reapply under the one-sided or two-sided model and to differentiate between whether the ACO will be applying for its first or second agreement period under Track 1 based on when the ACO terminated its previous agreement. Accordingly, we are finalizing the proposed changes to § 425.222(c), but are making additional revisions to clarify the treatment of previously terminated Track 1 ACOs that were in their second agreement period at the time of termination.

c. Modifications to the Track 2 Financial Model

To complement the proposals to extend ACOs' participation under Track 1 for a second agreement period to smooth the on ramp to risk, we proposed to modify the financial model under Track 2 for ACOs choosing this two-sided option to further encourage ACOs to accept increased performance-based risk. Specifically, we proposed to retain the existing features of Track 2 with the exception of modifying the threshold that Track 2 ACOs must meet or exceed in order to share in savings (minimum savings rate (MSR)) or losses (minimum loss rate (MLR)) from the current flat 2 percent to vary based upon the size of the ACO's assigned beneficiary population, as determined based on the methodology for setting the MSR under the one-sided model in § 425.604(b) as shown in Table 8. We explained in the December 2014 proposed rule that, as compared to the MSR used for Track 1, the flat 2 percent MSR/MLR generally offers a lower savings threshold for Track 2 ACOs to meet in order to share in savings, and

was established in recognition of the Track 2 ACOs' willingness to assume the risk of incurring shared losses (79 FR 72807). The proposal to vary the Track 2 MSR/MLR based on the number of beneficiaries assigned to the ACO would reduce risk for smaller ACOs by increasing the threshold before they would have to share in additional costs that they incur for the program. In turn, smaller ACOs would also have to achieve a greater level of savings under a higher MSR in order to share in savings (79 FR 72807). We explained our belief that by building in greater downside protection, this proposal might help smooth the on-ramp to performance-based risk for ACOs, particularly ACOs with smaller assigned populations and those with less experience with population management, making the transition to a two-sided model more attractive. With the proposed addition of Track 3 to the program, discussed later in this section, we explained that Track 2 could be viewed as a first step for some organizations to accepting performance-based risk.

TABLE 6—PROPOSED MINIMUM SAVINGS RATE AND MINIMUM LOSS RATE FOR TRACK 2

Number of beneficiaries	MSR/MLR (low end of assigned beneficiaries) (%)	MSR/MLR (high end of assigned beneficiaries) (%)
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0
60,000 +	2.0%	

We explored other ways to reduce financial risk for ACOs participating under Track 2, such as increasing the MSR/MLR using a fixed percent. For example, we considered using an MSR and MLR threshold of 3 or 4 percent that would apply to all ACOs participating in Track 2. We sought comments on this proposal as well as other options that could potentially make Track 2 more financially attractive to ACOs. We requested that commenters indicate why they believe an alternative option would be more attractive to ACOs than the one proposed and the specific reason why the option would be beneficial. We also requested that commenters consider whether additional safeguards should be implemented to appropriately protect

the Medicare Trust Funds, if an alternative approach were to be adopted.

Comment: Commenters generally agreed with our concern that the existing Track 2 features may not be sufficiently attractive for ACOs to take on performance-based risk. In particular, some commenters favored protecting Track 2 ACOs with smaller patient populations from losses, and for this reason supported higher MLRs for these ACOs. Several commenters, who favored limiting ACOs' exposure to risk, seemed to misunderstand the function of a higher MLR as being more protective of ACOs against financial risk.

Commenters for and against the proposed modification were fairly

evenly divided. Some commenters supported our proposal to modify both the MSR and MLR to vary based on the size of the ACO's assigned population, stating that the variable rate would add protection from losses for smaller ACOs and encourage participation in Track 2. Several commenters suggested that if a variable rate were to be used in Track 2, the range be narrowed, for example to a range of 1.5 through 2.5 percent (or no more than 2 percent) based upon the size of the ACO's assigned population. A commenter, who supported the proposal, explained that the proposed methodology based on standard inferential statistics reduces the probability of rewarding or punishing changes in expenditures which could be attributed to normal variation.

Others opposed changes to current policy which would increase the MSR/MLR and recommended that we retain the flat 2 percent MSR/MLR for Track 2 ACOs. A commenter explained that ACO participants willing to take on risk should be rewarded with a lower MSR, not one that is the same as the MSR used in a non-risk track. Several commenters explained the need to keep the MSR/MLR low to motivate Track 1 ACOs to make the transition to Track 2, suggesting that a variable MSR could make the track very unattractive relative to Track 1 and act as a disincentive for ACOs to move into performance-based risk. Several commenters explained that many small and rural ACOs believe they are disadvantaged by being held to a MSR of 3.9 percent when larger ACOs have a MSR of 2.0 percent. These commenters indicated that CMS' proposal provided strong disincentives for small and rural entities to move into Track 2, as they would need to achieve almost twice the amount of savings as larger ACOs in order to receive a shared savings bonus.

Still others recommended alternative modifications to the MSR/MLR under Track 2, with some commenters' suggestions about modifying the MSR/MLR emerging from their descriptions of alternatives to make performance-based risk more attractive under Tracks 2 and 3 as opposed to comments specifically on the proposed revisions to the Track 2 MSR/MLR. Suggestions included—

- Permitting the ACO to choose its own MSR/MLR. Many commenters favored an approach that would allow ACOs a choice of options including: A fixed MSR/MLR of 2.0 percent, no MSR/MLR, or a variable MSR/MLR (for example, between 2–3.9 percent based upon number of assigned beneficiaries). Commenters explained that each organization is in the best place to determine the level of risk for which it is prepared, and thus should be given options to choose from, rather than being required to have a specific fixed or variable MSR and MLR. Several commenters indicated that allowing ACOs the choice of MSR/MLR would encourage ACOs to transition to the two-sided model and encourage participation in the program generally. Several commenters explained that a MSR/MLR are not necessary as normal variation will result in inaccuracies both above and below the benchmark that will balance each other out. However, a commenter—

- Favored not lowering the MSR/MLR below 1 percent, concerned it could result in savings or losses based on

normal variation in utilization instead of changes in care for beneficiaries;

- Using a lower flat percent MSR/MLR, such as 1 percent; and
- Making the MLR variable (ranging from 2.0–3.9 percent) while using the flat 2 percent for the MSR. In this way, the ACO would be better protected from sharing in losses while enjoying a greater opportunity to share in savings.

Another commenter suggested that the MLR range be broadened to be higher, such as 4 percent; and setting the MLR higher, for example, at 5 percent, and allowing for a gradual reduction in the MLR over the course of time (for example, 1 percentage point per year) to ease the transition into risk.

A few commenters responded to CMS' request for feedback on whether additional safeguards should be implemented to appropriately protect the Medicare Trust Funds, if an alternative approach were to be adopted. A commenter specified that additional provisions are not needed to safeguard the Medicare Trust Funds because Medicare stands to benefit more from the participation of ACOs compared to the lack of participation by these organizations in the program altogether. Another commenter explained that the preservation of symmetry in the MSR/MLR creates protection for CMS.

Another commenter generally urged caution in making significant changes to the MSR/MLR rates going forward as such changes could negatively impact organizational planning. A commenter emphasized the importance of making the MSR/MLR the same under Track 2 and 3, to ensure equity across all ACOs assuming two-sided risk.

Response: We are persuaded by commenters' statements that ACOs are best positioned to determine the level of risk which they are prepared to accept. We also agree with commenters that ACOs under the two-sided model should be allowed to select from a range of MSR/MLR options. Given the relatively even divide among commenters favoring and disfavoring the proposal to vary the Track 2 MSR/MLR by the number of assigned beneficiaries, we are also convinced this methodology is one of several options that ACOs should be allowed to choose from. However, we disagree with the options suggested by commenters to modify the range (for example, to lower the minimum or increase the maximum) based upon the ACO's number of assigned beneficiaries. We developed this range based on the range established for Track 1 ACOs in the initial rulemaking establishing the Shared Savings Program, and as a

commenter pointed out, it was established based on standard inferential statistics. This approach reduces the probability of rewarding or punishing changes in expenditures which could be attributed to normal variation. We believe some ACOs want to have their MSR/MLR set based on this methodology. We also believe that increasing the MLR much higher above 3.9 percent may provide too great of a shield for ACOs entering the two-sided model. Therefore, it could foster the transition to risk by ACOs who have no intention of driving meaningful change in the quality and cost of the care furnished to their Medicare FFS beneficiaries.

In defining the other MSR/MLR options for ACOs to choose from, as a commenter pointed out, we believe it is important to preserve a symmetrical up-and-down-side. We also agree with the comment that ACOs accepting performance-based risk should have the option to choose an MSR/MLR as low as 0 percent, since an ACO in this position would have a significant incentive to make meaningful changes in the quality and cost of care for its beneficiaries since it would be liable for risk beginning at the first dollar. To maximize flexibility on the MSR/MLR in response to comments expressing concerns that the MSR is too onerous, we believe it is also appropriate to offer ACOs a choice of a symmetrical MSR/MLR in increments of 0.5 percent between 0.5 percent and 2.0 percent.

Therefore, we are modifying our proposal in order to give an ACO in Track 2 the ability to choose from a menu of options for setting its MSR and MLR for the duration of its agreement period. The menu of choices, reflecting our desire to retain symmetry between upside and downside risk, includes—

- Remove the MSR/MLR (the ACO shares in savings/losses from the first dollar);
- Select a symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent; and
- Implement a MSR/MLR that varies based on the size of the ACO's assigned population according to the methodology established under the one-sided model.

Track 2 ACOs would have the opportunity to select their MSR/MLR prior to the start of their agreement period, as part their initial program application or agreement renewal application. No modifications to this selection would be permitted during the course of the agreement period.

We believe that allowing Track 2 ACOs to customize their symmetrical MSR/MLR threshold for risk vs reward,

and implementing an identical approach under Track 3, is responsive to commenters' requests for greater flexibility in setting the threshold the ACO must meet before the ACO is eligible to share in savings or be accountable for losses. Further, we believe offering ACOs a choice of MSR/MLR will encourage ACOs to move to two-sided risk. For instance, ACOs who are more hesitant to enter a performance-based risk arrangement may choose a higher MSR/MLR, to have the protection of a higher threshold on downside risk, although they would in turn have a higher threshold to meet before being eligible to share in savings. ACOs who are comfortable with a lower threshold to protect them against risk of losses, may select a lower MSR/MLR to benefit from a corresponding lower threshold for sharing in savings. We also believe that applying the same MSR/MLR methodology in both of the two risk-based tracks reduces complexity for CMS' operations and establishes more equal footing between the risk models.

FINAL ACTION: We will retain the existing features of Track 2 with the exception of revising § 425.606(b) to allow ACOs entering Track 2 for agreement periods beginning January 2016 or later a choice among several options for establishing their MSR/MLR: (1) 0 percent MSR/MLR; (2) symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent; and (3) symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under the one-sided model. Regarding this third option, the MSR for an ACO under Track 2 will be the same as the MSR that would apply in the one-sided model under § 425.604(b) and is based on the number of beneficiaries assigned to the ACO, and the MLR must be equal to the negative MSR. We are also adopting a requirement that ACOs must select their MSR/MLR prior to the start of each agreement period in which they participate under Track 2 and this selection may not be changed during the course of the agreement period.

3. Creating Options for ACOs That Participate in Risk-Based Arrangements

a. Overview

We proposed to develop a new risk-based Track 3 under § 425.610 which would be based on the current payment methodology under Track 2, but would also incorporate some different elements that may make it more attractive for entities to accept increased performance-based risk. We structured the features of Track 3 in light of our

experience with the Shared Savings Program, comments from stakeholders, and early responses to the Pioneer ACO Model. In developing this new track, we aimed to encourage organizations to take on increasing financial risk in order to motivate even greater improvements in care and also to minimize the barriers faced by some ACOs that limit their willingness to accept performance-based risk. In evaluating what features might encourage ACOs to take on increasing financial risk, we considered several options, including modifying Track 1, modifying or eliminating Track 2, adding a new Track 3 to supplement the existing tracks, or a combination of these options.

In general, unless otherwise stated, we proposed to model Track 3 off the current provisions governing Track 2, which in turn are modeled on Track 1, and specifically to have the same general eligibility requirements, quality performance standards, data sharing requirements, monitoring rules, and transparency requirements. However, as we discuss later in this section, we proposed certain discrete features for Track 3 that differentiate it from Track 2. Specifically, we proposed to make modifications to the beneficiary assignment methodology, sharing rate, and performance payment and loss sharing limits.

Establishing Track 3 would require us to exercise our authority under section 1899(i)(3) of the Act, which requires that we determine that this policy: (1) “. . . does not result in spending more for such ACO for such beneficiaries than would otherwise be expended . . . if the model were not implemented;” and (2) “. . . will improve the quality and efficiency of items and services furnished under this title.” We applied this authority when proposing a two-sided risk-based model in our April 2011 proposed rule (76 FR 19603), which was modified and made final in our November 2011 final rule (76 FR 67909). As discussed in our final rule (76 FR 67904), we stated our belief that Track 2 would provide an opportunity for organizations more experienced with care coordination and risk models that are ready to accept performance-based risk to enter a sharing arrangement that provides greater reward for greater responsibility. In the December 2014 proposed rule (see 79 FR 72809), we expressed our belief that proposed Track 3 would offer an additional opportunity for ACOs to accept greater responsibility for beneficiary care in exchange for the possibility of greater reward. Moreover, we explained our belief that adding a second two-sided risk model would not result in an

increase in spending beyond what would otherwise occur. As discussed later in our Regulatory Impact Analysis of this final rule, our initial estimates suggested that the inclusion of Track 3 along with the other modifications to the program regulations would improve savings for the Trust Funds resulting from this program. Further, in the December 2014 proposed rule we explained our belief that adding Track 3 would improve the quality of care furnished to Medicare FFS beneficiaries because ACOs participating under Track 3 would have an even greater incentive to perform well on the quality measures in order to maximize the percentage of savings they may receive, while limiting their liability for any losses that might be incurred.

In this section we discuss our final actions on our proposed policies related to the creation of Track 3.

Comment: The majority of commenters providing feedback on the proposed Track 3 generally supported the addition of the new performance-based risk model based on prospective beneficiary assignment and offering ACOs multiple paths toward more accountable care. Many commenters supported the additional risk for greater reward that was offered under proposed Track 3 in relation to Track 2, with some commenters indicating that the addition of Track 3 will help beneficiaries realize the benefits of better care faster. A commenter specified the importance of allowing multiple risk-bearing tracks to enable ACOs to match their infrastructure and maturity to the appropriate regulatory framework. However, some commenters suggested modifications to Track 2 to make it closely match Track 3 (such as the balance of risk and reward, assignment, and availability of waivers, beneficiary attestation), calling into question the role of Track 2 in the program. A commenter suggested CMS eliminate Track 2 and offer only Tracks 1 and 3 to encourage transition to performance-based risk.

A few commenters were critical of the need for CMS to establish Track 3. A commenter supported CMS' interest in developing additional risk-based options, but suggested that actual implementation of Track 3 was premature, pointing out that few ACOs have entered Track 2. Therefore, few ACOs may be ready to take on the additional risk under Track 3. This commenter encouraged CMS to continue to gather and incorporate stakeholder feedback into the design of a Track 3. A commenter supported creation of a Track 3 generally, but suggested that it may not be needed if

much broader modifications were made to the design of the program's financial methodology.

Response: We appreciate commenters' support for Track 3 as a new option for a two-sided model under which ACOs have the opportunity to share in greater reward for accepting higher levels of risk. We agree with commenters who suggested the need to maintain Track 2 in addition to implementing Track 3 and to distinguish the features of these two-sided risk tracks to offer ACOs options, particularly with regard to assignment methodology and their level of risk and reward. As discussed in detail in the following sections, we are finalizing Track 3 with features that distinguish it from Tracks 1 and 2.

b. Assignment of Beneficiaries Under Track 3

Having considered the relative advantages and disadvantages of prospective and retrospective assignment methodologies for achieving improvements in the cost and quality of the care furnished to FFS beneficiaries, we proposed to implement a prospective assignment methodology, but only for Track 3 ACOs. The proposed design features were as follows:

- Using the same stepwise assignment methodology under § 425.402 to assign beneficiaries to ACOs participating under Track 3 as is currently used to assign beneficiaries to ACOs participating under Track 1 and Track 2. The result would be a prospective list of beneficiaries.

- Retrospectively excluding only those beneficiaries that appeared on the prospective assignment list that no longer meet eligibility criteria for assignment. The net effect would be to hold Track 3 ACOs accountable for beneficiaries who were prospectively assigned to the ACO based on having received primary care services from ACO professionals in the past, which would include beneficiaries that have received care from ACO professionals in the past, but who do not receive care from ACO participants during the performance year. This proposal reduces our concern that ACOs in Track 3 may avoid at-risk beneficiaries that appear on their prospective assignment list because they would be held accountable for the care of those beneficiaries, regardless of whether or not they choose to receive a plurality of their primary care services from ACO professionals.

- Basing prospective assignment on a 12-month assignment window (offset from the calendar year) prior to the start of the performance year. We further

proposed to define an "assignment window" as the 12-month period used to assign beneficiaries to an ACO and to make conforming changes to the regulations to refer to the assignment window where appropriate.

- Prohibiting beneficiaries that are prospectively assigned to a Track 3 ACO from being assigned to any other Shared Savings Program ACO as part of the retrospective reconciliation for Track 1 and Track 2 ACOs.

(1) Prospective Versus Retrospective Assignment

In the November 2011 final rule that established the Shared Savings Program, we adopted a preliminary prospective assignment model with retrospective reconciliation because it would provide ACOs with adequate information to redesign their care processes while also encouraging ACOs to standardize these care processes for all Medicare FFS beneficiaries instead of focusing care management activities on a small subset of their FFS population. Further, we expressed our view that this approach would provide sufficient incentives for each ACO to provide quality care to its entire beneficiary population (76 FR 67864).

As an alternative, beneficiaries could be prospectively assigned to an ACO prior to the start of the performance year. In the December 2014 proposed rule, we discussed the use of prospective alignment in the Pioneer ACO Model, where beneficiaries are aligned to Pioneer ACOs prior to the start of each performance year. Under the Pioneer ACO Model, the list of prospectively aligned beneficiaries is reconciled at the end of the year to exclude certain beneficiaries from the list, for example, beneficiaries who were not eligible for alignment during the performance year; however, no new beneficiaries are added to the list. We explained that this alternative assignment methodology arguably provides Pioneer ACOs with a more targeted set of FFS beneficiaries on whom to focus their care redesign efforts during the performance year. Further, we noted that this improved certainty may be an important factor in an ACO's willingness to take on greater performance-based risk because the ACO may be better positioned to make decisions regarding where to make investments in infrastructure to deliver enhanced services.

We proposed to implement a prospective assignment methodology for Track 3 ACOs using the assignment algorithm that is specified in Subpart E of the Shared Savings Program regulations, and described in more

detail in section II.E. of this final rule. This prospective assignment methodology would use the same stepwise assignment methodology under § 425.402 to assign beneficiaries to ACOs in Track 3 as is used to assign beneficiaries to ACOs participating under Track 1 and Track 2. The major difference would be that beneficiaries would be assigned to Track 3 ACOs prospectively, at the start of the performance year, and there would be no retrospective reconciliation resulting in the addition of new beneficiaries at the end of the performance year. The only adjustments that would be made at the end of the performance year would be to exclude beneficiaries that appeared on the prospective assignment list provided to the ACO at the start of the performance year that no longer meet eligibility criteria. For the reasons discussed in the November 2011 final rule (76 FR 67851), we explained that this proposed prospective assignment methodology meets the requirement under section 1899(c) of the Act that assignment be based on the "utilization of primary care services" provided by physicians that are ACO professionals. We also proposed to amend the regulations at § 425.400(a) by adding a new paragraph (3) to reflect this new prospective assignment methodology for Track 3.

We also sought comment on whether we should consider implementing the prospective assignment approach proposed for Track 3 under Track 2 and whether doing so would enhance or erode the incentives for organizations to take on risk.

Comment: Only a few commenters expressed reservations about moving to a prospective assignment model. A commenter strongly opposed implementing a prospective approach to assignment under any circumstances, expressing concerns that such an approach would result in inequalities of care by inappropriately shifting the ACO's focus to specific patients. Instead, the commenter stated that the current assignment methodology reduces potential inequalities in care by encouraging ACOs to redesign care processes to provide high quality and lower cost care to all FFS patients equally.

Nearly all commenters were generally supportive of implementing a prospective approach to assignment under Track 3. Commenters suggested that a prospective approach will permit ACOs to focus on specific beneficiaries and more generally on a stable assigned population, and consequently provide some certainty regarding where the ACO should focus its quality and cost efforts.

Commenters specifically detailed the following perceived benefits of prospective assignment:

- Allows ACOs to better apply population management techniques, including developing more effective systems to actively manage care for patients and engage patients.
- Gives providers stronger incentives to engage beneficiaries and their caregivers in care management activities; enables providers to focus on building long term relationships with patients.
- Allows ACOs to establish stabilized financial targets.
- Encourages transparency with assigned beneficiaries compared to retrospective assignment. Specifically, prospective assignment enables patients to be fully aware of any incentives providers may have in delivering their care and allows them to incorporate this understanding into the interactions they have with their care providers. Absent this information, patients may develop distrust in the system and unnecessarily switch physicians in order to opt-out of a program in which they may not even be included.

Other commenters pointed to challenges with the program's current preliminary prospective assignment methodology with retrospective reconciliation noting that it could stand in the way of ACOs achieving program goals and discourage participation in the program. In particular, commenters pointed to the quarterly churn of beneficiaries under the present assignment methodology as creating uncertainty for planning and implementing population health strategies and services and posing challenges for ACOs to accurately gauge the impact of new care programs and protocols. Given these challenges, a few other commenters expressed strongly that retrospective assignment should be eliminated from the program.

A comment reflected the commenter's misunderstanding that prospective assignment would limit beneficiaries to seeking care within the ACO. The commenter, supporting prospective assignment, explained that the current retrospective assignment methodology makes managing the cost and care of patients difficult because patients can seek primary care services from multiple providers, which can result in the patient no longer being assigned to an ACO.

Many commenters generally encouraged CMS to extend the option for prospective assignment beyond Track 3 to Tracks 1 and 2. Commenters emphasized the need for ACOs to know in advance the populations for which

they are responsible to most effectively coordinate care for such individuals and benefit from the other perceived advantages of prospective assignment (previously noted). Some commenters expressed the need for ACOs in Track 1 to become familiar with prospective assignment, and other features considered for Track 3, to prepare them to enter performance-based risk arrangements that include these features. Others explained that for Track 2 ACOs to be successful, they should have the benefit of the Track 3 features, including prospective assignment, to give them greater certainty over their assigned populations.

Other commenters saw the value in both assignment methodologies—knowing upfront who the ACO's assigned population is under prospective assignment versus accountability for a population that is retroactively determined to have actually received the plurality of its care from ACO providers/suppliers—and encouraged CMS to allow all ACOs (Tracks 1, 2, and 3) a choice of prospective and retrospective assignment. Several commenters suggested CMS allow ACOs a choice of retrospective or prospective assignment annually, within the ACO's 3-year agreement period. A commenter suggested allowing rural ACOs the option to elect prospective assignment.

Several commenters emphasized the importance of beneficiary attestation in relation to assignment. A commenter, responding to the request for comment about extending prospective assignment to Track 2, explained that prospective assignment would not necessarily be preferable to the current retrospective assignment under Track 2, unless a methodology was implemented whereby a beneficiary would attest to affirm his or her prospective assignment to the ACO prior to being assigned to the ACO, and the ACO was able to offer incentives, such as reduced cost sharing, to the beneficiary for receiving services within the ACO's network. Another commenter suggested that CMS allow ACOs the option to have patients assigned exclusively based on patient designation (attestation) instead of based on retrospective or prospective assignment.

Several comments reflect the need to better analyze the impact of assignment on beneficiaries' care. A commenter encouraged CMS to compare beneficiary awareness and satisfaction scores between the different assignment models (retrospective and prospective) to test the theory that prospective assignment increases beneficiary awareness, which in turn improves

patient satisfaction. If either or both of these increase, the commenter encouraged CMS to expand the prospective assignment methodology to the other Tracks. A commenter disagreed with CMS' belief that retrospective assignment offers strong incentives for health system redesign to impact the care for all FFS beneficiaries that receive care from ACO providers/suppliers, and that retrospective assignment limits the potential for gaming and reduces the motivation to target beneficiaries for avoidance. The commenter suggested ACOs should be encouraged to pilot innovative approaches on a subset of beneficiaries to determine their efficacy prior to full-scale implementation.

Response: We appreciate commenters' support generally for incorporating prospective assignment into the Shared Savings Program under a new performance-based risk option, Track 3. We continue to believe that the preliminary prospective assignment methodology with retrospective reconciliation currently used under Tracks 1 and 2 of the Shared Savings Program offers strong incentives for health system redesign to impact the care for all FFS beneficiaries receiving care from ACO providers/suppliers, as indicated in a commenter's remarks. We also continue to believe that the preliminary prospective assignment methodology with retrospective reconciliation limits the potential for gaming and reduces the motivation to target beneficiaries for avoidance. While comments indicate strong support for prospective assignment, and incorporating prospective assignment across all tracks of the program, we are also convinced by comments encouraging us to allow ACOs a choice of assignment methodology. We also acknowledge there is operational complexity and administrative burden to implementing an approach under which ACOs in any track may choose either prospective or retrospective assignment, with an opportunity to switch their selection on an annual basis. Therefore, we decline at this time to implement prospective assignment in Track 1 and Track 2, and we also decline to give ACOs in Track 3 a choice of either prospective or retrospective assignment. Further, we believe implementing prospective assignment in a two-sided model track may encourage Track 1 ACOs who prefer this assignment methodology, and the other features of Track 3, to more quickly transition to performance-based risk. We note that while prospective assignment will provide an ACO with the

knowledge at the beginning of each performance year of the population for which it will be accountable, this methodology does not eliminate the issues underlying beneficiary churn in an ACO's population. Specifically, Medicare fee-for-service beneficiaries retain their freedom to seek care from the Medicare-enrolled providers and suppliers of their choosing, including providers and suppliers within and outside an ACO. As the performance year progresses, the ACO or the provider/supplier that has provided the plurality of a beneficiary's primary care services may change. In the case of ACOs participating under Track 3, these changes will not affect their prospectively assigned population for the particular performance year, but will likely influence assignment of beneficiaries in the next performance year.

FINAL ACTION: We are finalizing our proposal to codify at § 425.400(a)(3) a prospective assignment methodology that would use the stepwise assignment methodology under § 425.402 to assign beneficiaries to ACOs in Track 3. Although beneficiaries will be assigned prospectively to Track 3 ACOs, the assignment methodology itself (specified under § 425.402) will be the same as is used to assign beneficiaries to ACOs participating under Track 1 and Track 2, with the limited exceptions that are discussed in this section such as the assignment window.

(2) Exclusion Criteria for Prospectively Assigned Beneficiaries

In the December 2014 proposed rule, we noted that changes in circumstance may cause prospectively assigned beneficiaries to no longer be eligible for assignment to an ACO at the end of a performance year. We explained that it is appropriate to exclude from an ACO's prospectively assigned population beneficiaries that are no longer eligible to be assigned to an ACO. We proposed to perform a limited reconciliation where beneficiaries would only be removed from the prospective assignment list at the end of the year if they were not eligible for assignment at that time under the criteria in proposed § 425.401(b). For example, if a prospectively assigned beneficiary chose to enroll in Medicare Advantage (MA) at the beginning of the performance year, that beneficiary would be removed from the beneficiary assignment list at the end of the year and the beneficiary's expenditures would not be used in determining the ACO's financial performance for that year. We noted that under this proposal, beneficiaries would be removed from

the prospective assignment list, but would not be added as they are in the retrospective reconciliation used under Tracks 1 and 2. We also explained that unlike the preliminary prospective assignment methodology with retrospective reconciliation used in Tracks 1 and 2, under this proposal, beneficiaries would not be removed from the prospective beneficiary assignment list because the beneficiary chose to receive the plurality of his or her primary care services during the performance year from practitioners other than those participating in the ACO. In other words, the ACO would be held accountable for all beneficiaries that appear on the prospective assignment list, with the narrow exception of those beneficiaries who are not eligible for assignment at the time of reconciliation based on the limited set of proposed exclusion criteria under proposed § 425.401(b). We explained that this methodology would help to mitigate concerns that ACOs may attempt to avoid caring for high risk beneficiaries that appear on their prospective beneficiary assignment list because the ACO will continue to be held accountable for the quality and cost of the care furnished to these beneficiaries even if the ACO providers/suppliers are not directly involved in their care. We also noted that this may mean that ACOs will be held accountable for beneficiaries with whom their ACO providers/suppliers have had little contact during the year. Therefore they may have limited opportunity to affect their care. We sought comment on our proposal to apply limited exclusion criteria to reconcile the prospective beneficiary assignment lists for ACOs under Track 3 at the end of the performance year.

Comment: Some commenters specifically expressed support for the proposed exclusion criteria. Many commenters offered suggestions on how to expand the proposed assignment exclusion criteria and their suggestions often included the exclusion of beneficiaries—

- Who opt out of data sharing.
- Who are cared for in long-term care (post-acute) facilities such as skilled nursing facilities or assisted living facilities.
- Who reside in the ACO's service region but receive care outside the ACO; for instance excluding beneficiaries who seek care from non-ACO providers/suppliers and in particular from distant tertiary/quaternary care facilities.
- Who move out of the ACO's service region.
- Based on the ACO's recommendation.

Some commenters specifically supported the exclusion of beneficiaries who enroll in Medicare Advantage at the beginning of the year, as indicated in the proposed exclusion criteria.

Several commenters suggested revisions to the assignment algorithm in relation to prospective assignment. A commenter suggested CMS should also adjust the assignment methodology to increase stability in the prospectively assigned population. For instance, if a beneficiary is initially assigned to an ACO in 1 year, the methodology should make it more likely for the beneficiary to be assigned to the ACO in subsequent years. Another commenter suggested that a beneficiary should remain assigned to a Track 3 ACO unless the beneficiary receives no primary care services during the performance year from an ACO professional within the Track 3 ACO whose services are considered at step 1 of the assignment methodology, and receives at least one primary care service from a primary care provider who is not an ACO professional in the Track 3 ACO whose services are considered at step 1 of the assignment methodology. A commenter suggested modifying the program's assignment methodology to limit assignment to beneficiaries living in the ACO's pre-defined service area.

Commenters provided the following operational considerations related to the limited reconciliation of the Track 3 ACOs' prospective assignment lists:

- Provide ACOs with notification, during the performance period, when beneficiaries are excluded.
- Remove beneficiaries who are excluded from the ACO's quality sample for the year.

Response: We are finalizing with modification our proposal to reconcile Track 3 ACOs' preliminary assignment lists based on the limited set of proposed exclusion criteria under § 425.401(b). While we appreciate the varied suggestions for additional assignment exclusion criteria suggested by commenters, we decline to adopt commenters' suggestions because we believe adding such exclusions would dilute the request for a prospective understanding of the population assigned to the ACO, lessen the distinction between a prospective approach and our current methodology, and raise concerns regarding avoidance of at-risk beneficiaries. We did, however, explore some of the commenters' suggestions. In particular, we performed an initial analysis on the suggestion for removal of beneficiaries who move out of the ACO's service area, based on the experience of the Pioneer ACO Model, and determined there is a

very small number (on average less than 2 percent) of beneficiaries who would meet the criteria for exclusion on this basis, and would not represent a significant portion of the ACO's assignment list. We believe that continuing to include these beneficiaries on the ACO's prospective assignment list during the performance year in which the move occurs provides an opportunity for ACOs to make sure beneficiaries who move from the ACO's service area have a seamless transition in care to the new primary care provider of their choice. We intend to monitor and assess the potential impact of these additional exclusion criteria suggestions made by commenters and, if appropriate, will propose adjustments in future rulemaking.

We also decline to adopt at this time revisions to the program's assignment algorithm, as suggested by commenters, to improve ACO's retention of assigned beneficiaries from year to year or to remove certain beneficiaries based on the type of providers who furnished their care.

We appreciate commenters' support for the proposal to annually remove beneficiaries from the Track 3 ACO's prospective assignment list, based on the proposed exclusion criteria, at the end of each benchmark and performance year. We also appreciate the comments on operational issues associated with performing only an annual reconciliation of the Track 3 ACO's assignment list. We agree that there may be circumstances where we need to perform this assignment list reconciliation more frequently than annually, for instance to facilitate feedback to ACOs on their quarterly program reports (which currently include a list of excluded beneficiaries) as well as in developing ACOs' quality reporting samples. Accordingly, we are modifying our proposal to perform an annual reconciliation of the Track 3 ACO's assignment list, to exclude beneficiaries ineligible for assignment under the proposed exclusion criteria, to provide for reconciliation of the Track 3 ACO's assignment list on a quarterly basis, to coincide with the provision of quarterly reports to ACOs. In addition, consistent with the approach currently used under Tracks 1 and 2, we expect to use recently available assignment data in determining the ACO's quality reporting sample, in order for the ACO to know in advance of the quality reporting period the beneficiaries for whom it must report quality measures.

Comment: A commenter suggested that CMS allow ACOs an opportunity for a reconsideration review of their

assignment list with respect to any beneficiaries the ACO believes were assigned in error.

Response: As discussed in the November 2011 final rule, certain actions specified in section 1899(g) of the Act are precluded from judicial and administrative review, including the assignment of Medicare fee-for-service beneficiaries to an ACO under subsection 1899(c) of the Act. Because beneficiary assignment under all tracks is under this authority, we are unable to offer a reconsideration review of beneficiary assignment lists.

FINAL ACTION: We are finalizing our proposed policy of excluding beneficiaries from the prospective assignment list for an ACO participating under Track 3, who meet the exclusion criteria, as specified at § 425.401(b), at the end of a performance or benchmark year. However, we are adopting a modification to this policy under which we will also perform this exclusion on a quarterly basis during each performance year, and incorporate these exclusions into quarterly reports provided to Track 3 ACOs. We have revised § 425.401(b) to reflect this change. In addition, we will use recently available assignment data when determining the ACO's quality reporting sample.

(3) Timing of Prospective Assignment

We proposed to base prospective assignment on a 12-month assignment window (off-set from the calendar year) prior to the start of the performance year. We further proposed to define an "assignment window" at § 425.20 as the 12-month period used to assign beneficiaries to an ACO. The assignment window for Tracks 1 and 2 would be based on a calendar year while the assignment window for Track 3 would be based on the most recent 12 months for which data are available, and which would be off-set from the calendar year. We proposed to make conforming changes to the regulations to refer to the assignment window where appropriate. We explained that this approach best balances the availability of claims data with the following operational considerations that affect the timing of when we would perform prospective assignment and make the assignment lists available to the ACOs:

- The importance of providing ACOs their assignment lists close to the start of each performance year.
- Operationally, the time needed to generate these lists.
- Aligning the timing of prospective assignment with the timing of annual acceptance of new ACOs into the program.

We also considered the option of using complete claims data for the calendar year prior to the performance year. Under this option, assignment would synchronize with the timing of the financial calculations for setting the ACO's benchmark, and would occur more than 3 months after the start of the performance year. However, under these parameters, Track 3 ACOs would not receive their prospective assignment lists until after the first quarter of each performance year. We believe that Track 3 ACOs would find such a delay in the receipt of their prospective assignment list burdensome for carrying out their health care operations, including care coordination processes and data analysis.

Comment: Commenters addressing these issues supported CMS' proposal to base prospective assignment on a 12-month assignment window (off-set from the calendar year), to balance the timely delivery of the ACO's assignment list against the availability of complete data for the calendar year prior to the start of the performance year. Some commenters expressed concern that CMS did not specify in the proposed rule the exact timeline it would use to determine prospective assignment, and urged CMS to provide this specificity in the final rule.

Several commenters explicitly stated support for the proposal to define an "assignment window" under § 425.20 as the 12-month period used to assign beneficiaries to an ACO.

Response: We appreciate the commenters' support of the proposal to base prospective assignment under Track 3 on a 12-month assignment window (off-set from the calendar year). In the proposed rule we provided an example of the timing of the 12 month period, which would span October through September of the prior calendar year. Specifically, to establish the assignment list for the performance year beginning January 1, 2016, we could use an assignment window from October 1, 2014 through September 30, 2015. We intentionally did not specify the precise months that would be used as part of the assignment window in the regulatory text to provide us operational flexibility in implementing assignment.

FINAL ACTION: We are finalizing our proposal regarding the timing of beneficiary assignment under Track 3, and will base prospective assignment on a 12-month assignment window (off-set from the calendar year) prior to the start of the performance year. Accordingly, we are finalizing the provision at § 425.400(a)(3) as proposed. In addition, we are finalizing our proposal, to define an "assignment window" at § 425.20 as

the 12-month period used to assign beneficiaries to an ACO.

(4) Interactions Between Prospective and Retrospective Assignment Models

Under the Shared Savings Program, a beneficiary may only be assigned to a single ACO for purposes of determining the ACO's financial and quality performance during a performance year. In the December 2014 proposed rule we explained that because there are markets in which there are multiple ACOs, there would likely be interactions between prospective assignment for Track 3 ACOs and preliminary prospective assignment with retrospective reconciliation for Track 1 and Track 2 ACOs. Accordingly, we proposed the following:

- A beneficiary that is prospectively assigned to a Track 3 ACO would remain assigned to the Track 3 ACO for the performance year even if the beneficiary chose to receive a plurality of his or her care outside the ACO.
- A beneficiary would remain assigned to the Track 3 ACO even if we determine as part of the retrospective reconciliation for Track 1 and Track 2 ACOs that the beneficiary actually received the plurality of his or her primary care from ACO professionals in another ACO.
- A beneficiary prospectively assigned to a Track 3 ACO would remain assigned to that ACO even if we subsequently determine the beneficiary actually received the plurality of his or her primary care from ACO professionals participating in another Track 3 ACO.

In other words, we proposed that once a beneficiary is prospectively assigned to a Track 3 ACO, the beneficiary will not be eligible for assignment to a different ACO, even if the beneficiary chose to receive a plurality of his or her primary care services from ACO professionals in that ACO during the relevant performance year.

Comment: Commenters were generally supportive of the proposal that a beneficiary prospectively assigned to a Track 3 ACO at the start of a performance year would not be eligible for assignment to a different ACO for that performance year. Several commenters suggesting additional assignment exclusion criteria (previously discussed) further suggested that some beneficiaries excluded from a prospective assignment list should become eligible for assignment to other ACOs (for example, in the case of a beneficiary who moved out of the ACO's area).

Several commenters suggested that CMS use the following hierarchy to

determine the order of precedence for beneficiary assignment:

- Beneficiary choice through attestation at any time during the year.
- Prospective assignment.
- Retrospective assignment.

Commenters explained that this hierarchy creates the most stable population for the ACOs, while first honoring beneficiary choice.

Response: We appreciate commenters' suggestions on the proposal concerning interactions between prospective assignment for Track 3 ACOs and preliminary prospective assignment with retrospective reconciliation for Track 1 and Track 2 ACOs. We are finalizing, as proposed, the policy establishing that a beneficiary prospectively assigned to a Track 3 ACO will not be eligible for assignment to a different ACO, even if the beneficiary chooses to receive a plurality of his or her primary care services from ACO professionals in that ACO during the relevant performance year. Specifically a beneficiary—

- That is prospectively assigned to a Track 3 ACO would remain assigned to the Track 3 ACO for the performance year even if the beneficiary chose to receive a plurality of his or her care outside the ACO;
- Would remain assigned to the Track 3 ACO even if we determine as part of the retrospective reconciliation for Track 1 and Track 2 ACOs that the beneficiary actually received the plurality of his or her care from ACO professionals in another ACO; or
- That is prospectively assigned to a Track 3 ACO would remain assigned to that ACO even if we subsequently determine the beneficiary actually received the plurality of his or her primary care from ACO professionals participating in another Track 3 ACO.

Since we are finalizing prospective assignment exclusion criteria for Track 3 consistent with the exclusion criteria used in Tracks 1 and 2, there is no opportunity for beneficiaries removed from Track 3 ACOs' assignment lists to be eligible for assignment to Track 1 or 2 ACOs.

We also wish to clarify that this policy on interactions between the prospective and retrospective assignment models would apply to assignment for benchmark years as well as assignment for performance years. Applying the same policies to benchmark year calculations as are applied to performance year calculations will reduce the chances of introducing unwanted bias.

As discussed elsewhere in this final rule, we will be proposing the procedures for beneficiary attestation in

rulemaking for the 2017 Physician Fee Schedule. However, our future considerations on how to incorporate beneficiary attestation into the Shared Savings Program will include commenters' suggestions about the need for an assignment hierarchy (accounting for attestation in relation to prospective and retrospective assignment).

FINAL ACTION: We are finalizing the policy that once a beneficiary is prospectively assigned to a Track 3 ACO for a benchmark or performance year the beneficiary will not be eligible for assignment to a different ACO, even if the beneficiary chose to receive a plurality of his or her primary care services from ACO professionals in that ACO during the relevant benchmark or performance year.

c. Determining Benchmark and Performance Year Expenditures Under Track 3

We proposed to use the same general methodology for determining benchmark and performance year expenditures under Track 3 as is currently used for Tracks 1 and 2, with the exception of certain modifications to account for the timing of beneficiary assignment under the prospective assignment methodology. Specifically, under § 425.602 we would establish the historical benchmark for all ACOs by determining the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period using the ACO participant TINs identified at the start of the agreement period (§ 425.602(a)). For each benchmark year that corresponds to a calendar year, this includes calculating the payment amounts included in Parts A and B fee-for-service claims using claims received within 3 months following the end of the calendar year (referred to as a "3 month claims run out") with a completion factor, excluding IME and DSH payments and considering individually beneficiary-identifiable payments made under a demonstration, pilot or time limited program (§ 425.602(a)(1)).

We proposed that in establishing the historical benchmark for Track 3 ACOs, we would determine the beneficiaries that would have been prospectively assigned to the ACO during each of the 3 most recent years prior to the start of the agreement period; basing benchmark year assignment on a 12-month assignment window offset from the calendar year prior to the start of each benchmark year. We also proposed to add a new regulation at § 425.610 to

address the calculation of shared savings and losses under Track 3.

We further proposed that we would still determine the Parts A and B fee-for-service expenditures for each calendar year, whether it is a benchmark year or a performance year, using a 3-month claims run out with a completion factor for the prospectively assigned beneficiaries. We would exclude IME and DSH payments and account for individually beneficiary-identifiable payments made under a demonstration, pilot or time limited program during the calendar year that corresponds to the benchmark or performance year. For example, for an ACO entering Track 3 beginning January 1, 2016, we would determine the benchmark based on CYs 2013, 2014, and 2015. We would determine a prospective list of beneficiaries using the assignment window for each year (based on an offset 12 month period such as October 1, 2011 through September 30, 2012 for BY1). However, the claims used to determine the per capita expenditures for BY1 would be based on claims submitted during the calendar year from January 1, 2013 through December 31, 2013. The same pattern would be used to determine assignment and per capita expenditures for BY2 and BY3. We would apply the same pattern going forward to calculate per capita expenditures for the performance years.

We noted that the timing of the generation of historical benchmark reports for Track 3 ACOs would also be consistent with the current schedule for generating these reports for ACOs in Tracks 1 and 2. That is, for an ACO that begins under Track 3 in 2016, the prospective beneficiary assignment list would be available immediately at the beginning of the performance year and the historical benchmark report would be available following the 3-month claims run out, sometime after the first quarter of 2016.

Comment: Commenters supported CMS' proposal to use the calendar year to calculate benchmark and performance year expenditures for beneficiaries assigned to ACOs under Track 3, and explained advantages of this approach: (1) Aligns with the actuarial analyses that calculate the risk scores and the data inputs based on national FFS expenditures (for example, the national trend factors) and (2) allows CMS to maintain consistent timing for the generation of the historical benchmark reports across all 3 tracks.

Response: We appreciate commenters' support of the proposed policies. We are finalizing as proposed the policy of using the same general benchmarking methodology used under Tracks 1 and

2 for determining benchmark and performance year expenditures under Track 3, with certain modifications to account for the timing of beneficiary assignment under the prospective assignment methodology, as follows:

- In establishing the historical benchmark for Track 3 ACOs, determining the beneficiaries that would have been prospectively assigned to the ACO during each of the 3 most recent years prior to the start of the agreement period by basing assignment on a 12-month assignment window offset from the calendar year prior to the start of each benchmark year.

- Determining the Parts A and B fee-for-service expenditures for prospectively assigned beneficiaries each calendar year, whether it is a benchmark year or a performance year; using a 3-month claims run out with a completion factor; excluding IME and DSH payments, and considering individually beneficiary-identifiable payments made under a demonstration, pilot or time limited program.

FINAL ACTION: We are finalizing our proposal for calculating the historical benchmarks for Track 3 ACOs in accordance with § 425.602, by determining benchmark year expenditures for Track 3 ACOs using the calendar year expenditures for prospectively assigned beneficiaries, allowing for a 3-month claims run out, excluding IME and DSH payments and considering individually beneficiary-identifiable payments made under a demonstration, pilot or time limited program. We are also finalizing our proposal to add a new regulation at § 425.610 to address the calculation of shared savings and losses under Track 3, including use of a 3-month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year, excluding IME and DSH payments and considering individually beneficiary-identifiable payments made under a demonstration, pilot or time limited program.

d. Risk Adjusting the Updated Benchmark for Track 3 ACOs

Currently, under Track 1 and Track 2, the risk adjustment methodology differentiates between newly and continuously assigned beneficiaries, as defined under § 425.20. A newly assigned beneficiary is a beneficiary assigned in the current performance year that was neither assigned to nor received a primary care service from any of the ACO participants during the most recent prior calendar year. A continuously assigned beneficiary is a beneficiary assigned to the ACO in the current performance year that was either

assigned to or received a primary care service from any of the ACO participants during the most recent prior calendar year. As specified under §§ 425.604(a), and 425.606(a), we use updated CMS-HCC prospective risk scores to account for changes in severity and case mix for newly-assigned beneficiaries. We use demographic factors to adjust for these changes in severity and case mix for continuously assigned beneficiaries. However, if the CMS-HCC prospective risk scores for the continuously assigned population show a decline, we use the lower risk score to adjust for changes in severity and case mix for this population.

In the December 2014 proposed rule we explained that, as expressed in the November 2011 final rule (76 FR 67918), this approach to risk adjustment strikes a fair balance between accounting for changes in the health status of an ACO's population while not encouraging changes in coding practices for care provided to beneficiaries who remain continuously assigned to the ACO or avoidance of high risk beneficiaries. We stated that we believe that the existing risk adjustment methodology has been effective in achieving this balance under Tracks 1 and 2, which use a retrospective assignment methodology for purposes of financial reconciliation, and that it would be appropriate to apply a similar approach to risk adjusting the updated benchmark for Track 3 ACOs, even though we proposed a prospective beneficiary assignment methodology. As in the existing tracks, it is important to ensure that ACOs participating under Track 3 are not encouraged to modify their coding practices in order to increase the likelihood of earning shared savings; rather, shared savings should result from actual reductions in Medicare expenditures for assigned beneficiaries.

Therefore, we proposed to apply the same general risk adjustment methodology in Track 3, but to make certain refinements to our definitions of newly and continuously assigned beneficiaries at § 425.20 to be consistent with our proposed prospective assignment approach for Track 3. Specifically, we proposed to replace the reference to "most recent prior calendar year" with a reference to "the assignment window for the most recent prior benchmark or performance year." Thus, for Track 3 the reference period for determining whether a beneficiary is newly or continuously assigned will be most recent prior prospective assignment window (the 12 months off set from the calendar year) before the assignment window for the current performance year. The reference period

for determining whether under Track 1 or 2 a beneficiary is newly or continuously assigned will continue to be the most recent prior assignment window (the most recent calendar year). Our proposed risk adjustment methodology for Track 3 was reflected in the proposed new regulation at § 425.610(a).

Comment: Commenters expressed their support for this proposal. However, commenters expressed concerns generally about the program's risk adjustment methodology.

Response: We appreciate commenters' support for the proposal to use the risk adjustment methodology established under Tracks 1 and 2 for updating the historical benchmark for Track 3 ACOs with refinements to the definitions of newly and continuously assigned beneficiaries to be consistent with the prospective assignment approach proposed for Track 3. In section II.F.5 of this final rule, we discuss in greater detail our response to concerns expressed by commenters about the program's existing risk adjustment methodology.

FINAL ACTION: We are finalizing our proposed risk adjustment methodology for updating the historical benchmark for Track 3 ACOs under § 425.610(a). We are also finalizing our proposal to modify the definitions of newly and continuously assigned beneficiaries at § 425.20 to ensure they are consistent with prospective assignment under Track 3 and remain relevant to preliminary prospective assignment with retrospective reconciliation under Tracks 1 and 2.

e. Final Sharing/Loss Rate and Performance Payment/Loss Recoupment Limit Under Track 3

Currently, an ACO that meets all the requirements for receiving shared savings payments under the one-sided (Track 1) model can qualify to receive a shared savings payment of up to 50 percent of all savings under its updated benchmark, not to exceed 10 percent of its updated benchmark, as determined on the basis of its quality performance. Likewise, a Track 2 ACO can potentially receive a shared savings payment of up to 60 percent of all savings under its updated benchmark, not to exceed 15 percent of its updated benchmark. The higher sharing rate and performance payment limit under Track 2 were established as incentives for ACOs to accept greater financial risk for their assigned beneficiaries in exchange for potentially higher financial rewards. Additionally, a Track 2 ACO is accountable for between 40 to 60 percent of all losses above its updated

benchmark, depending on the ACO's quality performance. The amount of shared losses for which an ACO is liable, however, may not exceed 5 percent of its updated benchmark in the first performance year, 7.5 percent in the second performance year, and 10 percent in the third performance year and any subsequent performance year (§ 425.606(g)). In the November 2011 final rule (76 FR 67937), we stated that we believe these progressively higher caps on losses "achieve an appropriate balance between providing ACOs with security about the limit of their accountability for losses while encouraging ACOs to take increasing responsibility for their costs and protecting the Medicare Trust Funds." In the December 2014 proposed rule, we noted that under one of the payment arrangements available under the Pioneer ACO Model, a Pioneer ACO can qualify to receive up to 75 percent of shared savings, not to exceed 15 percent of its benchmark. Under this payment arrangement, Pioneer ACOs may also be responsible for shared losses of up to 15 percent of their benchmark.

In the December 2014 proposed rule, we considered options for increasing ACO participation in a performance-based risk track by improving the attractiveness of the final sharing rate and performance payment limit in a risk model. We explained that it is important to reward ACOs with a greater level of savings for taking on greater levels of risk. Further, we noted that it is important to draw a distinction between the sharing rates available under Track 2 and the proposed Track 3.

We discussed several options for increasing potential shared savings while also increasing risk for Track 3 ACOs as follows:

- Retaining the symmetry between the shared savings and shared losses methodologies under Track 3, such that an ACO with very high quality performance would not be allowed to lower its share of losses below 25 percent of losses, the equivalent of 1 minus the maximum sharing rate of 75 percent, while being eligible for a sharing rate of up to 75 percent.
- Holding Track 3 ACOs responsible for the maximum percentage of losses, that is, 75 percent, while allowing quality performance to protect them only to the same extent it protects Track 2 ACOs, such that ACOs with very high quality scores would limit their percentage of losses to 40 percent.
- Applying the same minimum and maximum shared loss rates used under Track 2: That is, the range of 40 percent to 60 percent, depending on quality performance, but the maximum shared

savings rate would be increased to 75 percent in order to encourage participation in a model with increased risk.

After considering these options, we proposed, and sought comment on, the following policies under Track 3 (specified under § 425.610):

- Shared savings rate of up to 75 percent in conjunction with accepting risk for up to 75 percent of all losses, depending on quality performance similar to Track 2 ACOs. Track 3 ACOs with high quality performance would not be permitted to reduce the percentage of shared losses below 40 percent.
- Performance payment limit not to exceed 20 percent of the Track 3 ACO's updated benchmark, and a loss recoupment limit of 15 percent of the Track 3 ACO's updated benchmark. We also sought comment on whether a shared loss rate of 40 percent was high enough to protect the Trust Funds or whether it should be increased, for example, to 50 percent or 60 percent. We also sought comment on whether our proposal to establish a range of 40 percent to 75 percent for shared losses should, in turn, impact the amount of shared savings available to Track 3 ACOs. For example, should we permit Track 3 ACOs to earn a parallel range of 40 percent to 75 percent of shared savings. In other words, once the ACO has met criteria for sharing in savings, the minimum guaranteed amount of shared savings would be 40 percent with a maximum of 75 percent.

We requested comment on the appropriate minimum percentage of shared losses under Track 3. We also sought comment on the appropriate percentage for the performance payment limit and loss recoupment limit and whether there are reasons to set these at 15 percent and 10 percent of the updated benchmark respectively, rather than our proposal of 20 percent and 15 percent respectively.

Finally, we proposed to make certain technical, conforming changes to § 425.606, which governs the calculation of shared savings and losses under Track 2, to reflect our proposal to incorporate a second two-sided risk model into the Shared Savings Program. We sought comments on these proposed changes and on any other technical changes to our regulations that may be necessary in order to reflect the proposal to add a new Track 3.

Comment: Several commenters expressed support generally for the proposal to "widen the performance payment and loss sharing limits" under Track 3 as compared to Track 2, specifically the proposal to offer Track

3 ACOs the potential to realize more savings, but also more losses compared to Track 2. Some commenters agreed with the mix of risk and reward offered to Track 3 ACOs under the proposed policies, while other commenters expressed support for some aspects of the proposed policies (typically favoring higher reward and lower risk), while others suggested a number of alternatives.

Nearly all commenters were supportive of increasing the sharing rate and performance payment limit under Track 3 and establishing a maximum loss rate of 75 percent and a minimum loss rate of 40 percent, stating this would differentiate Track 3 from Track 2 for ACOs willing to take on more risk for greater reward. Some commenters recommended increasing the sharing rate, for example, to 85 percent, and some commenters suggested lowering the maximum and minimum loss rates (for example, to max 40 percent and min 10 percent, respectively). A commenter requested clarification and the opportunity to review and comment on the quality performance required to reduce the shared loss requirement from 75 percent to 40 percent.

Several commenters favored alternatives to the proposed policies that would reduce the total losses Track 3 ACOs would be liable for as follows:

- Track 3 loss sharing should match Track 2. A commenter generally supported holding Track 3 ACOs to the same level of downside risk as Track 2 (rather than less) even with high quality performance.

- Lower the loss sharing rate maximum, for example to 40 percent. Commenters explained that paying 40 percent of losses is a sufficient deterrent to incentivize providers to avoid losses if at all possible. Setting the percentage higher could deter participation in two-sided risk models.

- Lowering the loss sharing rate minimum, for example to 10 percent. Commenters suggested that the loss sharing rate under Track 3 be reduced to a minimum of 10 percent based on quality performance to encourage continued investment in quality improvements, which should yield longer term cost savings.

Some commenters specifically supported the proposed performance payment limit (20 percent) and loss cap (15 percent). A few commenters suggested alternatives to the sharing and loss caps, suggesting a lower loss cap (for example, 10 percent), or phasing-in loss caps for Track 1 ACOs moving to Track 3 with progressively higher caps year to year, or using symmetrical caps on savings and losses consistent with

those used in commercial ACO financial models.

While it was not uncommon for commenters to acknowledge the current low participation in the two-sided model, a commenter cautioned CMS about the unattractiveness of the downside of Track 3 given the lack of participation in Track 2 with its shared loss rate of up to 60 percent and loss limit of 5 percent in year 1, 7.5 percent in year 2 and 10 percent in year 3. When compared with the level of risk required under Track 2, the commenter expressed concerns that the proposal to hold Track 3 ACOs accountable for a shared loss rate of up to 75 percent with a loss-recoupment limit of 15 percent would be counterproductive.

Response: We appreciate commenters' support for the proposed policies related to the final sharing and loss rates and performance payment and loss sharing limitations for Track 3, and are finalizing these features of Track 3 as proposed. We continue to believe that the proposed policies strike the appropriate balance between risk and reward under this new two-sided model Track. We believe that the opportunity for greater shared savings as compared to Track 2 will encourage ACOs to enter performance-based risk, as well as give an opportunity for greater reward for ACOs more experienced with population management who are achieving the program's goals. Further, offering greater risk and reward under Track 3 as compared to Track 2 creates another step towards progressively higher risk, which we believe is responsive to commenters' requests for additional program options. We continue to believe it is important to hold ACOs accountable for greater risk in exchange for the opportunity to earn a greater reward, particularly considering that we believe ACOs who bear financial risk hold the potential to induce more meaningful systematic change. For these reasons, we disagree with the suggestions to lower the maximum loss sharing rates and the loss limits for Track 3 to match, or to be lower than, those currently offered under Track 2.

As commenters pointed out, participation in the two-sided model has been low. We believe the features of the financial model under Track 3, as well as opportunities for prospective assignment and additional programmatic and regulatory flexibility for Track 3 ACOs will attract ACOs to enter this model.

FINAL ACTION: We are finalizing the following modifications in order to implement a new two-sided risk option, Track 3 under § 425.610:

- Applying a shared savings rate of up to 75 percent in conjunction with accepting risk for up to 75 percent of all losses, depending on quality performance similar to Track 2 ACOs. Track 3 ACOs with high quality performance would not be permitted to reduce the percentage of shared losses below 40 percent.

- Applying a performance payment limit such that shared savings do not exceed 20 percent of the Track 3 ACO's updated benchmark, and a loss recoupment limit of 15 percent of the Track 3 ACO's updated benchmark.

We did not receive any comments on the technical, conforming changes to § 425.606 to reflect our proposal to incorporate a second two-sided risk model into the Shared Savings Program, and we are finalizing these changes as proposed.

f. Minimum Savings Rate and Minimum Loss Rate in Track 3

We proposed to apply the same fixed MSR and MLR of 2 percent under Track 3, as was originally established for Track 2 under the November 2011 final rule. This proposal was reflected in paragraph (b) of the proposed new regulation at § 425.610. As described in the December 2014 proposed rule, we also considered other options for establishing the MSR and MLR for Track 3 ACOs, including an option that would remove the MSR and MLR entirely. Under this option, ACOs would be subject to normal variation around their benchmark so that they would be held responsible for all losses when performance year expenditures are above the benchmark in addition to sharing in any savings if performance year expenditures fall below the benchmark. Another option could be to set both the MSR and MLR at 1 percent instead of 2 percent. This would serve to increase both risk of sharing losses and savings, but not as much as doing away with the MSR and MLR entirely. We specifically sought comment on whether it would be desirable to remove the MSR and MLR entirely under Track 3 as well as alternative levels at which to set the MSR and MLR for ACOs participating under Track 3. We noted that we would consider comments received regarding these alternatives in determining the final MSR and MLR that would apply under Track 3.

Comment: Several commenters expressed support for our proposals to apply a fixed 2 percent MSR/MLR to Track 3 ACOs, favoring an alternative that would differentiate Track 3 from Track 2 (where we proposed to revise the MSR/MLR to vary based upon the size of the ACO's population) and

provide a greater opportunity to share savings for Track 3 ACOs. Some commenters offered alternatives such as permitting ACOs to choose a MSR/MLR that varies by number of assigned beneficiaries, choose their own MSR/MLR, use a flat 1 percent MSR/MLR, or eliminate it altogether. We consider the comments received in response to the proposed modification of the MSR/MLR for Track 2 to be relevant to our proposal and the options we sought comment on for setting the MSR/MLR for Track 3. (See related discussion in section F.2.c of this final rule.)

Response: As we previously explained in our response to the comments on our proposed revisions to the MSR/MLR for Track 2, we are persuaded by commenters' statements that ACOs are best positioned to determine the level of risk they are prepared to accept. We are finalizing the same MSR/MLR methodology for ACOs in both Track 2 and 3. Under this methodology, ACOs may select a symmetrical MSR/MLR to apply throughout the course of their agreement period from a set of options. We believe that applying this same flexibility in symmetrical MSR/MLR selection across Tracks 2 and 3 is appropriate, and would allow ACOs to have the opportunity to select the risk track to best suit their preferences and their readiness to accept performance-based risk. We believe commenters supportive of the proposed policy would find this policy acceptable, as Track 3 ACOs would have the opportunity to choose a flat 2 percent MSR/MLR (as was proposed). Furthermore, we believe this approach is responsive to commenters' requests for greater flexibility on the thresholds ACOs must meet to be eligible to share in savings or be accountable for sharing in losses under Track 3.

Under this policy, Track 3 ACOs would have the opportunity to select a symmetrical MSR/MLR prior to the start of their agreement period, as part their initial program application or agreement renewal application. No modifications to this selection would be permitted during the course of this agreement period.

FINAL ACTION: We are finalizing a MSR/MLR methodology for Track 3 under § 425.610(b) that will allow ACOs to choose among several options for establishing their symmetrical MSR/MLR: (1) 0 percent MSR/MLR; (2) symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent; and (3) symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under the one-

sided model. Under the third option, the MSR for an ACO under Track 3 would be the same as the MSR that would apply in the one-sided model under § 425.604(b) and is based on the number of beneficiaries assigned to the ACO. The MLR under Track 3 must be equal to the negative MSR. We are also finalizing a requirement that ACOs must select their MSR/MLR prior to the start of each agreement period in which they participate under Track 3 and this selection may not be changed during the course of the agreement period.

Additionally, we are making conforming changes to § 425.100 to account for the addition of Track 3. Section 425.100(c) currently refers to the application of the minimum loss rate to ACOs that operate under the two-sided model. In the December 2014 proposed rule, we proposed to make a conforming change to § 425.100(c) to add references to the two-sided models under Tracks 2 and 3. In this conforming change, we inadvertently included a reference to the one-sided model (§ 425.604). Accordingly, in this final rule, we are modifying the conforming change to eliminate the reference to the one-sided model because ACOs under this model are not accountable for shared losses.

g. Monitoring for Gaming and Avoidance of At-Risk Beneficiaries

In the December 2014 proposed rule we explained that while we have concerns that prospective assignment may inadvertently increase incentives for gaming and avoidance of at-risk beneficiaries, we have taken steps to minimize these incentives by retaining other Shared Savings Program policies and procedures such as risk-adjusting expenditures and monitoring ACOs to ensure they are not engaging in gaming or avoidance of at-risk beneficiaries. We explained further that our proposal to exclude only those beneficiaries that no longer meet the eligibility criteria for assignment to an ACO should reduce the probability that attempts by the ACO to "cherry pick" or avoid at-risk beneficiaries during the performance year would succeed. Therefore, the concerns associated with a prospective assignment methodology would be balanced by the potential that establishing a new Track 3 has to encourage ACOs to accept greater responsibility and financial risk for the care provided to their patients in return for the possibility of achieving greater rewards. We sought comment on ways to mitigate concerns regarding gaming and avoidance of at-risk beneficiaries under a prospective assignment methodology, whether implementing a

prospective approach to assignment would dilute the program goals of delivery system redesign, and whether there are additional programmatic considerations that should be taken into account as a result of our proposal to apply a prospective assignment methodology in Track 3.

Comment: Several commenters expressed general concerns about the effect of ACOs undertaking increased financial risk and prospective assignment on beneficiaries' freedom of choice of providers and, more generally, on access to care. In particular, commenters expressed concerns that ACOs that transition to risk-based models have incentives to curtail access to care provided in certain settings or by certain providers, specifically post-acute and rehabilitation care and care by specialty and sub-specialty providers. Some commenters explained that performance-based risk could increase the likelihood for care stinting and beneficiary steering. A commenter explained that prospective assignment may tempt ACOs to treat their assigned beneficiary populations as if they are enrolled managed care populations and apply more aggressive care management strategies that limit patient choice. A commenter generally suggested that ACOs have already implemented more aggressive and somewhat questionable practices that require patient referrals to remain within ACOs.

Several commenters explained their concerns were heightened in certain circumstances, such as situations in which ACOs do not include a broad range of specialists, and, as a result, patients may not have access to appropriate specialty care for their clinical needs. Concerns were also raised regarding the program's existing quality measurement and risk adjustment methodology. Several commenters indicated that the program's existing quality measures are not sufficient to assure appropriate levels of care even under existing levels of risk. Another commenter specified that the Clinician and Group CAHPS for ACOs survey used to assess ACO quality performance is not sufficient to demonstrate whether beneficiaries are being referred for specialty care at the most clinically appropriate point in their disease progression. A commenter suggested that avoidance behavior around high-risk beneficiaries could be eliminated by including robust risk adjustment that incorporates all of beneficiaries' health related characteristics (clinical complexities), as well as relevant socioeconomic and socio-demographic factors.

Some commenters provided the following suggestions on how to protect against care stinting, beneficiary steering and avoidance of at-risk beneficiaries by ACOs under prospective assignment:

- Examine the referral patterns of ACOs.
- Establish benchmarks that will foster an appropriate level of access to and care coordination with specialty medicine providers, particularly for beneficiaries with chronic health conditions.
- Require ACOs to include in their applications a summary of specialists included in their networks and the methodology used to determine that the number of specialists is sufficient to provide access to the assigned beneficiary population.
- Require ACOs to include specialists on committees responsible for developing and implementing care pathways for the ACO's assigned Medicare population.
- Develop formalized guidance for ACOs outlining the types of behaviors that are and are not allowed with regard to a prospectively assigned patient population.
- Closely monitor whether ACOs are limiting beneficiary freedom of choice in light of prospective assignment or discouraging high-cost or at-risk beneficiaries from seeking care at the ACO in order to avoid assignment of these beneficiaries to the ACO.
- Monitor for a combination of factors, such as quality performance, ACO Participant List changes, and utilization trends.
- Ensure beneficiaries understand their right to seek care from providers of their choice.

Response: As we discussed in the December 2014 proposed rule, we believe that ACOs will have strong incentives to provide their prospectively assigned beneficiaries high-quality, low-cost care in order to discourage them from seeking care outside the ACO and that beneficiaries that are prospectively assigned to an ACO will continue to be protected from concerns related to inappropriate limitations on care under traditional FFS Medicare because of their ability to choose their providers. Unlike managed care programs, there is no lock-in for beneficiaries under the Shared Savings Program. Beneficiaries assigned to Shared Savings Program ACOs retain their freedom to choose their healthcare providers and suppliers. Therefore, we believe a prospective assignment methodology under the Shared Savings Program presents limited risks to FFS beneficiaries.

We appreciate the commenters' sharing their concerns and recommendations on this issue. We agree that monitoring is necessary to ensure providers do not stint on care or avoid at-risk beneficiaries, and we currently monitor ACOs for these circumstances as specified under § 425.316(b). Our policies on monitoring and termination will help to ensure that ACOs who underperform on the quality standards do not continue in the program. Further, we continue to believe the program's quality performance standard is rigorous and the quality measures are diverse and appropriate, spanning ACO-reported measures, claims-based and administrative measures and patient/caregiver experience of care measures. We will monitor closely the implementation of prospective assignment and the effect of performance-based risk on ACOs, and if we identify concerns, we may revise our policies in these areas in future rulemaking.

4. Modifications to Repayment Mechanism Requirements

a. Overview

In the November 2011 final rule (76 FR 67937), we discussed the importance of a program requirement that ensures ACOs entering the two-sided model will be capable of repaying Medicare for shared losses. The final rule established a requirement that ACOs applying to participate in the two-sided model must establish a repayment mechanism to assure CMS that they can repay losses for which they may be liable (§ 425.204(f)). For an ACO's first performance year, the repayment mechanism must be equal to at least 1 percent of its total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries, as determined based on expenditures used to establish the ACO's benchmark (§ 425.204(f)).

Further, to continue participation in the program, each Track 2 ACO must annually demonstrate the adequacy of its repayment mechanism before the start of each performance year in which it takes risk (§ 425.204(f)(3)). The repayment mechanism for each performance year must be equal to at least 1 percent of the ACO's total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries, as determined based on expenditures for the ACO's most recent performance year.

An ACO may demonstrate its ability to repay losses, or other monies determined to be owed upon first year reconciliation, by obtaining reinsurance,

placing funds in escrow, obtaining surety bonds, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing another appropriate repayment mechanism that will ensure its ability to repay the Medicare program (§ 425.204(f)(2)). Given our experience in implementing the program, we proposed to revisit our requirements to simplify them and to address stakeholder concerns regarding the transition to risk, as discussed in the previous sections.

b. Amount and Duration of the Repayment Mechanism

In the proposed rule, we discussed that the practical impact of the current rule is to require ACOs to create and maintain two separate repayment mechanisms for 2 consecutive performance years, which effectively doubles the amount of the repayment mechanism during the overlapping time period between the start of a new performance year and settlement of the previous performance year. We heard from stakeholders that establishing multiple repayment mechanisms during the agreement period can be very burdensome and ties up capital that could otherwise be used to support ACO operations. Therefore, we considered whether it would be possible to streamline the repayment mechanism requirements. Specifically, we considered whether it would be feasible for an organization to establish a single repayment mechanism to cover the entire 3-year agreement period. Initially, we were concerned that requiring an organization to establish a single repayment mechanism to cover 3 performance years would involve excessive and overly burdensome repayment amounts. However, our actuaries determined that this may not be the case. Instead, we found that the repayment mechanism that is established for the first performance year of an agreement period under a two-sided risk model could be rolled over for subsequent performance years. In other words, we could create a mechanism for ACOs to demonstrate their ability to repay losses by establishing one repayment mechanism for the entire 3-year agreement period.

Thus, we proposed to require an ACO to establish a repayment mechanism once at the beginning of a 3-year agreement period. We additionally proposed to require an ACO to demonstrate that it would be able to repay shared losses incurred at any time within the agreement period, that is, upon each performance-year reconciliation and for a reasonable

period of time after the end of each agreement period (the “tail period”). Under our proposal, the tail period provides time for CMS to calculate the amount of any shared losses the ACO may owe and to collect this amount from the ACO. We proposed to establish the length of the tail period in guidance.

We proposed that an ACO must demonstrate the adequacy of its repayment mechanism and maintain the ability to repay 1 percent of the ACO’s total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries based on the expenditures used to establish the benchmark for the applicable agreement period, as estimated by CMS at the time of application or participation agreement renewal. If the ACO uses any portion of the repayment mechanism to repay any shared losses owed to CMS, the ACO must promptly replenish the amount of funds available through the repayment mechanism within 60 days. This would ensure continued availability of funds to cover any shared losses generated in subsequent performance years. Given that we also proposed, as discussed in section II.B. of this final rule, to adjust an ACO’s benchmark annually to account for changes in the ACO participant list, it is possible that an ACO’s benchmark could change such that the repayment mechanism amount established at the beginning of the 3-year agreement period no longer represents 1 percent of the ACO’s benchmark expenditures. Therefore, we noted in our proposal that we were considering whether to require the ACO to adjust the repayment mechanism to account for this change, or whether we should establish a threshold that triggers a requirement for the ACO to add to its repayment mechanism. We sought comment on this issue, including the appropriate threshold that should trigger a requirement that the ACO increase the amount guaranteed by the repayment mechanism.

We proposed to modify § 425.204(f) to reflect these changes. We noted that the reference to “other monies determined to be owed” in the current provision relates to the interim payments that were available in the first performance year only for ACOs that started participating in the program in 2012. Because we no longer offer interim payments to ACOs, we also proposed to remove from § 425.204(f) the reference to “other monies determined to be owed.”

Comment: We received several comments on our proposal to require an ACO to establish a repayment mechanism once at the beginning of the agreement period instead of annually.

Most commenters expressed support for this change because they believe it would reduce burden on the ACO. Few commenters opposed the change, but the ones that did stated that it may be more difficult or more expensive for an ACO to obtain a repayment mechanism that covers 3-performance years as opposed to one; for example, a commenter explained that the duration and size of a surety bond may affect whether an ACO can obtain a surety bond. As the duration of the bonded obligation becomes longer, the surety must predict the strength of the principal’s operation for periods of time further into the future, and this in turn increases the surety’s risk, resulting in tightened underwriting standards.

A commenter pointed out that there is nothing currently in the program rules to prohibit an ACO from replacing one repayment mechanism with another and suggested that CMS establish a policy to give ACOs flexibility to switch from one type of approved repayment mechanism to another. This same commenter believes such flexibility would enable the ACO to pursue its best option at any given time without jeopardizing CMS’ possession of a sound repayment mechanism.

Response: We appreciate these comments and agree with commenters that requiring an ACO to establish a repayment mechanism once at the beginning of an agreement period instead of annually could relieve burden from ACOs that choose to participate under a two-sided model. Thus, we anticipate that the proposed policy would be less burdensome than the current policy. Specifically, under the existing rule, a two-sided model ACO must concurrently maintain multiple repayment mechanism arrangements. For instance, an ACO must retain the repayment mechanism established for the preceding performance year while CMS determines the ACO’s shared savings or losses for that prior performance year while also maintaining a separate repayment mechanism for the current performance year. Based on our experience with repayment mechanisms, we believe ACOs will be able to work with financial institutions to establish the required arrangement to cover the full agreement period and tail period. However, we will monitor the use of repayment mechanisms and may revisit the issue in future rulemaking if we determine that the ability of an ACO to establish an adequate repayment mechanism for the entire agreement period and an appropriate tail period is constrained by the availability or cost of repayment mechanism options.

Furthermore, we agree that nothing in our program rules currently prohibits an ACO from changing from one acceptable repayment mechanism to another during the agreement period. Indeed, we worked with an ACO who transitioned from a letter of credit to an escrow account, and we anticipate changes where an ACO replaces a repayment mechanism with another acceptable repayment mechanism are likely to occur in the future. However, we note that these changes can be costly and require significant coordination between CMS, the ACO, and financial institutions to ensure the ACO remains in compliance with the program’s repayment mechanism requirements at all times during the transition. Therefore, we encourage ACOs to establish and maintain one repayment mechanism for the entire 3-year agreement period and tail period.

Comment: A few commenters provided feedback regarding the proposal to require ACOs to maintain a repayment mechanism sufficient to repay 1 percent of the ACO’s total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries based on the expenditures used to establish the benchmark for the applicable agreement period, as estimated by CMS at the time of application or participation agreement renewal. These few commenters found the proposed amount acceptable. A few commenters responded to CMS’ request for comment on whether a threshold should be established that triggers a requirement for the ACO to add to its repayment mechanism. Several commenters stated that such a trigger should apply, but only when the amount of the required payment mechanism would decline. In other words, the repayment mechanism should be revised only if the ACO’s benchmark declines. A commenter suggested that CMS conduct analyses on the magnitude of year-to-year changes in benchmarks prior to setting a threshold amount or trigger. This commenter explained it did not expect it to be common for an ACO to make changes to its ACO participant list significant enough so that the 1 percent initially estimated is no longer sufficient. Several commenters recommended specific triggers for revisions to the amount of the repayment mechanism such as changes in the ACO’s benchmark of 10 or 15 percent or more, or changes to the ACO participant list.

Response: We appreciate these comments and decline at this time to establish a trigger or threshold that would require an ACO to add to (or remove from) its repayment mechanism

in the event the ACO's benchmark changes significantly during the course of the agreement period. We agree with commenters that CMS should conduct the suggested additional analyses prior to implementing such a policy. We may revisit this issue in future rulemaking after we gain more experience with ACOs under a two-sided model.

Comment: Several commenters provided comment on the proposal that the ACO must promptly replenish the amount of funds available through the repayment mechanism within 60 days. Most commenters opposed the proposal stating that 60 days may not be enough to raise the necessary replenishment funds, particularly in ACOs that had accrued substantial losses. Instead, these commenters suggested permitting the ACO 90 days to replenish the repayment mechanism. A commenter found 60 days a reasonable period of time for replenishment. Other commenters expressed concern that ACOs that have used their repayment mechanisms may not be in a financial position to replenish the amount at all. These commenters suggested that requiring replenishment was unusual, particularly in the case of surety bonds, and recommended that CMS carefully consider whether such a policy would be necessary.

Response: We appreciate the comments regarding replenishment of repayment mechanism funds when they are used during the agreement period. We believe it is important for an ACO that uses a repayment mechanism for shared losses to replenish the arrangement so that the ACO continues to demonstrate its ability to repay any future losses during the agreement period. We disagree that requiring replenishment is particularly unusual, but we agree that some ACOs may require additional time to replenish funds. Specifically, we believe that ACOs who have used their existing repayment mechanism arrangement to repay shared losses might need additional time to gather the resources needed to replenish their repayment mechanism arrangement. Therefore, we are revising our proposal. Instead of requiring ACOs to replenish funds within 60 days, we will allow up to 90 days for replenishment. However, we will monitor the replenishment process and may revisit the issue in future rulemaking if we believe this policy inhibits ACO participation in the Shared Savings Program or undermines ACOs' ability to repay shared losses.

FINAL ACTION: We are finalizing our proposal to require an ACO that enters a two-sided model to establish a repayment mechanism once at the

beginning of a 3-year agreement period. We recognize there are a few ACOs under existing participation agreements in Track 2 that have established repayment mechanisms for the 2014 and 2015 performance years (the final 2 years of the ACO's first agreement period). We note that the repayment mechanisms established by these ACOs are types of repayment mechanisms that we are retaining under this final rule. Accordingly, we expect these ACOs to maintain their existing repayment mechanisms in accordance with the terms set forth in the repayment mechanisms. Should these ACOs choose to renew their participation agreements for a second agreement period beginning January 1, 2016, they will only need to establish a repayment mechanism once at the beginning of their new 3-year agreement period. For purposes of this final rule, we will treat the existing repayment mechanisms established by these ACOs for the 2014 and 2015 performance years as satisfying the requirement that the ACO establish a repayment mechanism that is sufficient to repay any shared losses it may incur in the current agreement period and will apply the revisions to the requirements under section § 425.204(f) accordingly.

Under the new requirements we are finalizing in this rule, ACOs must demonstrate that they would be able to repay shared losses incurred at any time within the agreement period, and for a reasonable period of time after the end of each agreement period (the "tail period"). The tail period shall be sufficient to permit CMS to calculate the amount of any shared losses that may be owed by the ACO and to collect this amount from the ACO. We will establish the length of the tail period in guidance. Additionally, we are finalizing our proposal that an ACO must demonstrate the adequacy of its repayment mechanism and maintain the ability to repay 1 percent of the ACO's total per capita Medicare Parts A and B FFS expenditures for its assigned beneficiaries based on the expenditures used to establish the benchmark for the applicable agreement period, as estimated by CMS at the time of application or participation agreement renewal. We decline at this time to adopt a policy to establish a trigger or threshold that would require an ACO to increase the value of its repayment mechanism in the event of changes to the ACO's benchmark during the agreement period.

We are modifying our proposal regarding the timing of the replenishment of the amount of funds available through the repayment mechanism. Based on comments, we are

finalizing the requirement that if an ACO uses its repayment mechanism to repay any portion of shared losses owed to CMS, the ACO must promptly replenish the amount of funds required to be available through the repayment mechanism within 90 days.

Finally, we are finalizing our proposal to modify § 425.204(f) to reflect these changes, and to remove the reference to "other monies determined to be owed" from § 425.204(f).

c. Permissible Repayment Mechanisms

Under our current rules, ACOs may demonstrate their ability to repay shared losses by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing another appropriate repayment mechanism that will ensure their ability to repay the Medicare program. Based on our experience with the program, we proposed to remove the option that permits ACOs to demonstrate their ability to pay using reinsurance or an alternative mechanism. First, in the proposed rule we explained that no Shared Savings Program ACOs had obtained reinsurance to establish their repayment mechanism. We noted that ACOs that explored this option had told us that it is difficult to obtain reinsurance, in part, because of insurers' lack of experience with the Shared Savings Program and the ACO model, and because Shared Savings Program ACOs take on performance-based risk rather than insurance risk. Additionally, the terms of reinsurance policies could vary greatly and prove difficult for CMS to effectively evaluate. Second, we explained that based on our experience to date, a request to use an alternative repayment mechanism increases administrative complexity for both ACOs and CMS during the application process and is more likely to be rejected by CMS than one of the specified repayment mechanisms.

Therefore, we proposed to revise § 425.204(f)(2) to limit the types of repayment mechanisms ACOs may use to demonstrate their ability to repay shared losses to the following: Placing funds in escrow; establishing a line of credit; or obtaining a surety bond. Under this proposed revision, ACOs would retain the flexibility to choose a repayment mechanism that best suits their organization. We stated that we would be more readily able to evaluate the adequacy of these three types of arrangements, as compared to reinsurance policies and other alternative repayment mechanisms. For

instance, escrow account agreements, letters of credit, and surety bonds typically have standard terms that CMS can more readily assess as compared to the documentation for alternative repayment mechanisms, which tends to be highly variable.

In addition, we proposed to clarify that ACOs may use a combination of the designated repayment mechanisms, if needed, such as placing certain funds in escrow, obtaining a surety bond for a portion of remaining funds, and establishing a line of credit for the remainder. Thus, we proposed to revise our rule at § 425.204(f)(2) to indicate that an ACO may demonstrate its ability to repay shared losses owed by placing funds in escrow, obtaining surety bonds, establishing a line of credit, or by using a combination of these mechanisms. We sought comment on our proposed modifications to the repayment mechanism requirements and also welcomed comments on the availability and adequacy of reinsurance as a repayment mechanism.

Comment: Commenters specific suggestions regarding repayment mechanisms that were not addressed directly by our proposals as follows:

- ACOs should be required to meet the same rigorous financial reserve and solvency requirements as state-regulated risk-bearing entities such as organizations participating in Medicare Advantage.
- CMS should subsidize the ACO's cost for establishing a repayment mechanism.
- CMS should establish standards for selecting institutions that issue letters of credit or hold funds in escrow, similar to the requirements for sureties to be authorized by the Department of Treasury.
- CMS should establish standardized forms for ACOs to use, for example, a standardized surety bond form.

Response: We appreciate these comments and will keep them in mind when developing future proposed rule changes. We decline at this time to adopt more stringent repayment mechanism standards because there are very distinct differences between Shared Savings Program ACOs and Medicare Advantage plans. Specifically, as noted in our 2011 final rule, we believe that organizations participating in the Shared Savings Program are taking on performance-based risk and not insurance risk, the latter of which is retained by Medicare because ACO participants continue to bill and receive FFS payments as they normally would. Additionally, we decline at this time to further reduce the burden of the repayment mechanism requirement on

ACOs, as suggested by commenters. We note that ACOs choosing to enter a two-sided model are required to accept additional up-front risk in exchange for the greater potential for reward. The cost of establishing a repayment mechanism is one additional up-front risk for ACOs. As we explained in November 2011 final rule, we believe that ACOs entering the two-sided model would likely be larger and more experienced ACOs or both, and thus have the experience, expertise and resources to meet the repayment requirements (76 FR 67940). Further, we believe the repayment mechanism requirement is an important safeguard against ACOs entering the two-sided model when they lack the capacity to bear performance risk. Adopting policies whereby CMS would subsidize the ACO's repayment mechanism would undermine the objectives of the repayment mechanism policy. We also decline at this time to require all ACOs, and their respective financial institutions, to use a specified format across all repayment mechanism instruments. We issued "Repayment Mechanism Arrangements Guidance," available online <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf>, to explain the terms we would expect to see in various repayment mechanism arrangements, but did not go so far as to require use of a specified form. Given the newness of the program and our lack of experience with these arrangements for ACOs, it was our desire not to impede ACOs from working with financial institutions to establish the most appropriate repayment mechanism for their circumstance.

Comment: Several commenters opposed our proposal to limit alternative repayment mechanism options for ACOs and encouraged CMS to retain flexibility for ACOs to choose the repayment mechanism that best suits it. In particular, these commenters stated that they believe it is too early to remove alternative repayment mechanisms and reinsurance as permitted mechanisms for demonstrating the ability to repay shared losses owed to CMS because having as many options for a repayment mechanism as possible would align with CMS' desire to encourage organizations to take on two-sided risk. Commenters explained that reinsurance is a well-established and proven means of managing risk that is frequently used by organizations that manage capitated risk in commercial insurance contexts

and that these policies are likely to become more available and standardized as ACOs and insurers gain more experience with shared savings models. A commenter went further and encouraged CMS to actively promote reinsurance as the best funding vehicle for successful ACOs, explaining that ACOs should create 'captive' insurance companies to holistically manage the emerging clinical, financial, and quality risks of the whole ACO enterprise. A commenter recommended that CMS retain an alternative repayment mechanism that would allow ACOs' shared losses to be carried over to subsequent years (for example, through deductions in FFS payments), rather than demanding full payment all at once.

On the other hand, a few commenters expressed specific support for the proposal to eliminate alternative repayment mechanisms and reinsurance as options for repayment stating that their removal would simplify program rules and options.

Response: As we indicated in our December 2014 proposed rule, based on our experience with the program to date, no Shared Savings Program ACOs have obtained reinsurance for the purpose of establishing their repayment mechanism. ACOs that explored this option told us that it is difficult to get reinsurance, in part, because of insurers' lack of experience with the Shared Savings Program and Medicare ACOs and because Shared Savings Program ACOs take on performance-based risk not insurance risk. In the proposed rule, we also explained that the terms of reinsurance policies for ACOs could vary greatly and prove difficult for CMS to effectively evaluate. In addition, based on our experience to date, an alternative repayment mechanism increases administrative complexity for both ACOs and CMS during the application process and we are more likely to reject it than one of the specified repayment mechanisms. However, we agree with stakeholders that reinsurance may become a viable option in the future. If it does, we intend to revisit this issue and may propose to add reinsurance as an option for ACOs to demonstrate their ability to repay shared losses owed to CMS. At this time, we continue to believe that CMS would be more readily able to evaluate the adequacy of the three remaining types of repayment arrangements, as compared to reinsurance policies and other alternative repayment mechanisms. In addition, ACOs may use a combination of the designated repayment mechanisms, if needed, such as placing

certain funds in escrow, obtaining a surety bond for a portion of remaining funds, and establishing a line of credit for the remainder.

FINAL ACTION: We are finalizing the revisions to our policy on repayment mechanisms. Specifically, we are finalizing the proposed revisions to our rule at § 425.204(f)(2) to indicate that an ACO may demonstrate its ability to repay shared losses owed by placing funds in escrow, obtaining surety bonds, establishing a line of credit, or by using a combination of these mechanisms.

5. Methodology for Establishing, Updating, and Resetting the Benchmark

a. Overview

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available three years of per beneficiary expenditures for parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for parts A and B services under the original Medicare fee-for-service program, as estimated by the Secretary. Such benchmark shall be reset at the start of each agreement period. Accordingly, through the initial rulemaking establishing the Shared Savings Program, we adopted policies for establishing, updating and resetting ACO benchmarks at § 425.602. Under this methodology, we establish ACO-specific benchmarks that account for national FFS trends.

As the statute requires the use of historical expenditures to establish an ACO's benchmark, the per capita costs for each benchmark year must be trended forward to current year dollars and then a weighted average is used to obtain the ACO's historical benchmark for the first agreement period. The statute further requires that we update the benchmark for each year of the agreement period based on the projected absolute amount of growth in national per capita expenditures for parts A and B services under the FFS program, as estimated by the Secretary. In the April 2011 proposed rule (76 FR 19609 through 19611), we considered a variety of options for establishing the trend factors used in establishing the historical benchmark and for accounting for FFS trends in updating the

benchmark during the agreement period.

The statute outlines the scope of Medicare expenditures to be used in calculating ACO benchmarks. Section 1899(d)(1)(B)(ii) of the Act specifies that the benchmark is established “. . . using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO.” This provision of the Act further specifies: “Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate.”

In addition to the statutory benchmarking methodology established in section 1899(d), section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under this title and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

Under the methodology established by the November 2011 final rule (§ 425.602) we calculate a benchmark for each ACO using a risk-adjusted average of per capita Parts A and B expenditures for original Medicare fee-for-service (FFS) beneficiaries who would have been assigned to the ACO in each of the three calendar years prior to the start of the agreement period. We trend forward each of the first 2 benchmark year's per capita risk adjusted expenditures to third benchmark year (BY3) dollars based on the national average growth rate in Parts A and B per capita FFS expenditures verified by the CMS Office of the Actuary (OACT). The first benchmark year is weighted 10 percent, the second benchmark year is weighted 30 percent, and the third benchmark year is weighted 60 percent. This weighting creates a benchmark that more accurately reflects the latest expenditures and health status of the ACO's assigned beneficiary population. In creating an updated benchmark we account for changes in beneficiary characteristics and update the benchmark by the OACT-verified projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original fee-for-service program. In trending forward, accounting for changes in beneficiary characteristics, and updating the benchmark, we make calculations for populations of

beneficiaries in each of the following Medicare enrollment types: ESRD, disabled, aged/dual eligible and aged/non-dual eligible. Further, to minimize variation from catastrophically large claims, we truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at a threshold of the 99th percentile of national Medicare FFS expenditures. Under section 1899(d)(1)(B)(ii) of the Act and § 425.602(c) of the Shared Savings Program regulations an ACO's benchmark must be reset at the start of each agreement period.

In the December 2014 proposed rule, we considered whether modifying the methodology used for establishing, updating, and resetting ACO benchmarks to account for factors relevant to ACOs that have participated in the program for 3 or more years would help ensure that the Shared Savings Program remains attractive to ACOs and continues to encourage ACOs to improve their performance, particularly those that have achieved shared savings. As discussed later in this section, we considered a range of modifications to the benchmarking methodology in order to expand the methodology for resetting benchmarks to account for factors relevant to continued participation by ACOs in subsequent agreement periods and to increase incentives to achieve savings in a current agreement period, specifically: (1) Equally weighting the three benchmark years; (2) accounting for shared savings payments in benchmarks; (3) using regional FFS expenditures (as opposed to national FFS expenditures) to trend and update the benchmarks; (4) implementing an alternative methodology for resetting ACO benchmarks that would hold an ACO's historical costs, as determined for purposes of establishing the ACO's initial historical benchmark for its first agreement period, constant relative to costs in its region for all of the ACO's subsequent agreement periods; and (5) implementing an alternative methodology for resetting ACO benchmarks that would transition ACOs to benchmarks based only on regional FFS costs, as opposed to the ACO's own historical costs, over the course of multiple agreement periods. Further, we considered whether to apply these changes broadly to all ACOs or to apply these changes only when resetting benchmarks for ACOs entering their second or subsequent agreement periods. We also considered whether to apply these changes to a subset of ACOs, such as ACOs participating

under a two-sided model (Tracks 2 and 3) or Track 3 ACOs only.

We considered and sought comment on using combinations of these approaches, as opposed to any one approach. Specifically, we considered revising the methodology for resetting ACO benchmarks by equally weighting the three benchmark years or accounting for shared savings payments received by an ACO in its prior agreement period or both, and using regional FFS expenditures instead of national FFS expenditures in establishing and updating the benchmark.

In considering these potential options for modifying the benchmarking methodology, we noted it is necessary to balance the desire to structure the program to provide appropriate financial incentives to ACOs with the need to protect the Medicare Trust Funds. We also noted the necessity of meeting the requirements for invoking our authority under section 1899(i) of the Act, where relevant.

Comment: Generally, commenters appreciated CMS' interest in modifying the program's current benchmarking methodology, particularly to improve the sustainability of the program. Commenters generally supported changes to the benchmarking methodology that would encourage continued participation and improvement by ACOs, thereby improving the program's sustainability. Some commenters suggested the need to improve the predictability, accuracy and stability of benchmarks over time. A commenter indicated that the revisions to the benchmarking methodology discussed in the proposed rule do not go far enough to address the program's inherent challenges to ACO success under the program, for instance pointing to the MSR.

Commenters pointed out the following perceived disadvantages of the program's current benchmarking methodology:

- Calculating the trend for the three years of the historical benchmark and the annual benchmark update using a national growth rate, or more generally not accounting for regional cost trends in benchmarks. Some commenters perceived disadvantages to ACOs in many regions because significant variation in year to year cost trends by market are not accounted for by using a single national dollar amount to update the benchmark.

- Existing rebasing methodology, based on ACO-specific historical spending, penalizes certain ACOs for past good performance and forces ACOs to chase diminishing returns in subsequent contract periods when the

benchmark is reset. Some described this dynamic as requiring the ACO to continually beat its own best performance, or as a "downward spiral," and by others as "chasing one's tail." Some identified this issue as being of particular concern to existing low-cost ACOs.

- Existing risk adjustment methodology doesn't completely account for the health status of assigned beneficiaries.

- Current rebasing benchmarking methodology (rebasings with each new agreement period) leads to unstable benchmarks; others connected unstable benchmarks with assigned beneficiary churn.

Some commenters offered a mix of views on the advantages and disadvantages of ACO-specific benchmarks. For instance, higher cost ACOs are advantaged with higher benchmarks. Therefore, they are rewarded for their historical organizational inefficiency. ACOs with lower costs may be discouraged from participating under this benchmarking methodology. Some commenters suggested benchmarks that include factors other than the ACO's historical performance would be more appropriate, while others explained that the benchmarks should primarily focus on the historical costs of the ACO's unique population.

Commenters expressed a mix of views over whether the benchmark methodology should be revised to address incentives for existing high-cost and low-cost ACOs. Some commenters expressed concern that the current methodology for establishing and resetting ACO benchmarks disadvantages ACOs with historically good performance, and strongly recommended against any benchmarking methodology that would disadvantage those ACOs with historically good performance. Some commenters, including MedPAC, expressed their opposition to policies that would result in higher benchmarks for all ACOs, even high-spending ACOs. Several commenters explained that the program's benchmark methodology needs to take into account how efficient ACOs are when entering the program, while also providing an appropriate incentive for ACOs to continue their participation in subsequent agreement periods.

Some commenters stated that it would be premature for CMS to finalize any benchmarking methodology changes at this time. These commenters stated that CMS should perform additional modeling and analytic work on the alternatives discussed in the proposed

rule and share the results of this analysis before putting forward detailed proposals on revisions to the benchmarking methodology through additional notice and comment rulemaking.

Response: We appreciate commenters' thoughtful consideration of the modifications to the benchmarking methodology we sought comment on in the December 2014 proposed rule. We agree with commenters who expressed that the benchmarking methodology is pivotal to the program's future direction, in terms of sustainability and the types of ACOs that choose to enter and remain in the program. In the following sections we discuss and finalize several modifications to our benchmarking methodology, which relate to the process for resetting the benchmark. These modifications are particularly important at this time in light of the upcoming rebasing for ACOs with 2012 and 2013 agreement start dates who elect to enter a second agreement period starting January 1, 2016. The comments made on these issues are important and were carefully considered in the developing the policies in this final rule, as well as in arriving at our decision, described in greater detail below, to pursue further rulemaking to make additional changes to the benchmarking methodology in the near future.

b. Modifications to the Rebasings Methodology

In the December 2014 proposed rule we discussed the possible implications of using the current benchmarking methodology when resetting the ACO's benchmark for its second or subsequent agreement period. We explained that by using the three historical years prior to the start of an ACO's agreement period in establishing benchmarks, an ACO's benchmark under its second or subsequent agreement period will reflect its previous performance under the program. Among ACOs whose assigned beneficiary population for purposes of resetting the benchmark closely matches their assigned beneficiary population for the corresponding performance years of the preceding agreement period, those ACOs that generated savings during a prior agreement period will have comparatively lower benchmarks for their next agreement period. Under these circumstances, we explained the application of the current methodology for establishing and weighting the benchmark years when resetting benchmarks could reduce the incentive for ACOs that generate savings or that are trending positive in their first

agreement period to participate in the program over the longer run or reduce incentives for ACOs to achieve savings in their first agreement period.

However, we also noted that a number of factors (such as changes in ACO participants) could affect beneficiary assignment for purposes of establishing ACO benchmarks in subsequent agreement periods, which may cause an ACO's benchmark in subsequent years and agreement periods to deviate from its benchmark established in the first agreement period.

To address concerns raised by stakeholders related to resetting benchmarks, we considered revising the methodology to equally weight benchmark years and account for shared savings earned by an ACO in its prior agreement period, as a way to encourage ongoing participation by successful ACOs and improve the incentive to achieve savings. We sought comment on these modifications, and whether, if adopted, these methodologies should be applied uniformly across all ACOs or only to ACOs who choose certain two-sided risk tracks.

(1) Equally Weighting the Three Benchmark Years

In the December 2014 proposed rule we sought comment on a methodology for resetting benchmarks in which we would weight the benchmark years equally (ascribing a weight of one-third to each benchmark year). We indicated, that if left unchanged, the application of the existing methodology for weighting the benchmark years at 10 percent for BY1, 30 percent for BY2 and 60 percent for BY3 when resetting benchmarks could reduce the incentive for ACOs that generate savings or that are trending positive in their first agreement period to participate in the program over the longer run, or reduce incentives for ACOs to achieve savings in their first agreement period. We explained that this alternative approach would have the most significant impact upon ACOs who generated savings during the preceding agreement period for an assigned beneficiary population that closely approximate the assigned beneficiary population used to determine their benchmark for the subsequent agreement period.

Comment: Many commenters supported equally weighting the three benchmark years, believing this change would likely result in more generous benchmarks compared to the existing methodology of weighting the benchmark years (10 percent BY1, 30 percent BY2, 60 percent BY3). In particular, this approach would help protect ACOs who had been successful

in generating savings in their prior agreement period against having to beat their own best performance in a second or subsequent agreement period. A commenter explained that equal weighting would result in a more gradual lowering of the benchmark calculations and allow ACOs the opportunity to earn more savings. Several commenters explained that interventions put in place in the first and second performance years of an agreement period will have the most impact in performance year 3 (which would become BY3 of the next agreement period) and their belief that equal weighting of the benchmark years would address this issue more effectively than the weighting approach under the current methodology. A commenter pointed to the use of equal weighting of baseline years in the later years of the Pioneer ACO Model.

Others disagreed with implementing this change explaining that the most accurate predictor of an ACO's costs would be based on expenditures from the year prior to the start of the ACO's agreement period. Many of these commenters seemed to favor the program's existing weighting approach of 10 percent BY1, 30 percent BY2, and 60 percent BY3. Several commenters expressed concern that equal weighting the benchmark years does not appear to adequately address changes in an ACO's composition over time, particularly for ACOs who have expanded/changed their geography and network.

A commenter disagreed with our conclusion about the likely impact of equal weighting on ACOs whose participant composition remains stable, explaining that a change to equal weighting would have minimal impact to ACOs with stable populations and costs. This commenter also indicated that equal weighting would not reflect inflationary costs.

A commenter pointed out a tradeoff with moving to equal weighting: making this modification may disadvantage ACOs that are struggling to achieve savings, but on the other hand without this change successful ACOs may be disproportionately punished for their success.

Several commenters suggested the following alternatives to the proposed policy:

- Apply equal weighting of the benchmark years beginning with the ACO's first agreement period.
- Equal weighting in the first and third agreement periods, but not the second. A commenter explained that by equally weighting the second agreement period's benchmark years there could be a perverse incentive to increase costs

substantially in the first agreement period to obtain a higher benchmark going into the second agreement period. However, the commenter pointed out the current weighting approach could create similar incentives to increase costs substantially in year 3 to obtain a higher benchmark. In either event, the ACO would then be entering its next agreement period in a very high cost position, jeopardizing future shared savings or exposing it to very high risk under the two-sided model.

- Equal weighting should be used in resetting benchmarks for ACOs who generated savings beneath their MSR (trending positive) under their prior agreement period.

A commenter recommended further analysis about the risk profile of beneficiaries assigned during benchmark years before switching to equal weighting.

Response: We appreciate commenters' support for the approach of equally weighting an ACO's benchmark years when resetting the ACO's benchmark under a second or subsequent agreement period and are revising the regulations to finalize this policy. We agree with commenters that if an ACO generates savings in its first agreement period it is likely that the impact on claims would be most significant in the second or third performance year as opposed to being uniformly distributed across all three performance years. As we explained in the December 2014 proposed rule, this hypothesis is supported by the following factors:

- There may be a lag between when an ACO starts care management activities and when these activities have a measurable impact upon expenditures for the ACO's assigned beneficiary population.

- ACOs may improve their effectiveness over time as they gain experience with population management and improve processes.

- There may be higher care costs during the early period of performance to treat or stabilize certain patients, as the ACO's care management activities involving these patients commence.

Once stabilized, these patients may show relatively lower care costs over the course of time due to more effective, coordinated and high quality care.

As we stated in the December 2014 proposed rule, we believe that under these circumstances, resetting the benchmark for ACOs starting a second or subsequent agreement period under the Shared Savings Program becomes a trade-off between the accuracy gained by weighting the benchmark years at 10 percent for BY1, 30 percent for BY2, 60 percent for BY3, and the potential for

further reducing the benchmarks for these ACOs by giving greater weight to the later performance years of the preceding agreement period. Consistent with the concerns raised by some commenters, we continue to believe that, if unchanged, the application of the current methodology for weighting the benchmark years when resetting benchmarks could reduce the incentive for ACOs that generate savings or that are trending positive in their first agreement period to participate in the program over the longer run, or reduce incentives for ACOs to achieve savings in their first agreement period. We believe an appropriate approach to addressing these concerns is equally weighting the benchmark years when resetting the ACO's historical benchmark for its second or subsequent agreement period. In particular, we believe this adjustment is one component of establishing a benchmark rebasing methodology to provide appropriate incentives for ACOs to improve and maintain high performance in subsequent agreement periods.

We continue to believe in the importance of maintaining the current weighting approach of 10 percent BY1, 30 percent BY2, and 60 percent BY3 when establishing the historical benchmark for an ACO's initial agreement period because giving the greatest weight to the ACO's most recent prior cost experience improves the accuracy of the benchmark. Therefore, we decline to apply this modified weighting approach to a subset of these ACOs, as suggested by some commenters, although we may revisit this decision in upcoming rulemaking on additional changes to the benchmarking methodology.

FINAL ACTION: We are revising § 425.602(c) to specify that in resetting the historical benchmark for ACOs in their second or subsequent agreement we will weight each benchmark year equally. More generally, we are also revising the title of provision 425.602 to clarify that it contains policies relevant to the original calculation of the benchmark at the start of an ACO's first agreement period and to the updates to the benchmark that are made during the agreement period and resetting the benchmark at the start of each subsequent agreement period.

(2) Accounting for Shared Savings Payments When Resetting the Benchmark

In the December 2014 proposed rule we sought comment on a methodology for resetting ACO benchmarks that would account for shared savings earned by an ACO in its prior agreement

period as a way to encourage continued participation by successful ACOs and improve the incentive to achieve savings. We indicated that we were considering an approach under which we develop per a beneficiary average based on the shared savings payment for the particular performance year under the prior agreement period and apply this adjustment on a per beneficiary basis to the assigned population for the corresponding benchmark year. We also sought comment on whether to make a symmetrical adjustment to the benchmarks for ACOs that owed losses in a previous agreement period. We noted that by making the adjustment only for ACOs that receive shared savings payments in their prior agreement period, some ACOs that reduce expenditures would not receive the benefit of this adjustment. Specifically, ACOs whose performance year expenditures are lower than their benchmark expenditures by an amount that did not meet or exceed their MSR, and ACOs that generated savings outside their MSRs but failed to satisfy the quality reporting standard, would not receive the adjustment. Additionally, we noted that the availability of performance data relative to timely creation of benchmarks would need to be addressed. We anticipate completing financial reconciliation for an ACO's most recent prior performance year midway through its current performance year. As a result, one implication of relying on the availability of performance data from the most recent prior performance year is that it would delay the finalization of an ACO's historical benchmark for its subsequent agreement period until well into the first performance year.

Comment: Many commenters supported a modified methodology for resetting an ACO's benchmark for its second or subsequent agreement period under which we would account for the ACO's shared savings in its prior agreement period. Some commenters urged CMS to add in all savings an ACO generated (as opposed to savings earned), for instance, to protect ACOs who generated savings below their MSRs, as well as to account for CMS' share of savings in this adjustment. A commenter suggested an alternative approach for reallocating savings between ACOs who met or exceeded their MSRs, and those who generated savings close to but beneath their MSR. Overall, commenters expressed that they believe that this change would make the historical benchmark more reflective of the total cost of care for the beneficiaries during the prior agreement

period and would ultimately encourage continued participation in subsequent agreement periods by not penalizing those ACOs who were able to make cost improvements.

Several commenters expressed concerns that these changes may not go far enough to adequately adapt the benchmark for future agreement periods. Several commenters indicated this approach would not adequately account for changes in the risk profile of the ACO's patient population. A commenter indicated that accounting for savings alone may only capture a percentage of the improvement (efficiencies) the ACO achieved, recommending for example, that CMS also adjust the ACO's MSR based on total savings produced for Medicare.

Another commenter, opposed to this approach, explained that including savings in rebasing will only widen the gap between low and high cost providers, and recommended that this approach not be used in the program's financial model.

Others urged CMS against including shared loss payments from an ACO's prior agreement period under the two-sided track, as this would make it even harder for struggling ACOs to generate savings under a new agreement period.

Response: We agree with commenters on the importance of accounting for the financial performance of an ACO during its prior agreement period in resetting the ACO's historical benchmark. In particular, we believe that this adjustment is important for encouraging ongoing program participation by ACOs who have achieved success in achieving the three-part aim in their first agreement, by lowering expenditures and improving both the quality of care provided to Medicare FFS beneficiaries and the overall health of those beneficiaries. Absent this adjustment, an ACO who previously achieved success in the program may elect to terminate its participation in the program rather than face a lower benchmark that reflects the lower costs for its patient population during the three most recent prior years.

We are further persuaded by commenters of the need to account for all savings between the benchmark and the ACO's MSR as well as savings that were generated and shared that met or exceeded the ACO's MSR. Specifically, we believe that accounting for any savings generated by the ACO in the previous agreement period would increase the benchmarks of ACOs who are working to achieve the program's goal of lowering growth in Medicare FFS expenditures. This way, ACOs who may have lowered expenditures, but not by enough to earn a performance

payment, will also benefit from this adjustment. However, we believe it is important to adjust the level of shared savings that we add into benchmark year expenditures to prevent a situation in which the reset benchmark becomes overly inflated based on prior performance to the point where ACOs need to do little to maintain or change their care practices in order to generate savings.

At the time of this final rule, there is limited data available on ACO financial performance because results from the second and third performance years for ACOs seeking to begin their second agreement period on January 1, 2016 are not yet available. We are particularly concerned about finalizing a rebasing policy that would advantage an ACO who underperforms based on cost and quality experience, and we are seeking to target adjustments to ACOs that have been successful in the program but who may face challenges in continuing to build on that success in subsequent agreement periods. Therefore, we are finalizing an approach whereby we will account for savings generated by an ACO in rebasing its benchmark if the ACO generated net savings across the three performance years under its first agreement period, and will also account for the ACO's quality performance in each performance year under its first agreement period. We will also limit the adjustment to the benchmark for the second agreement period to the average number of assigned beneficiary person years under the ACO's first agreement period. We believe imposing this limit is important in order to help ensure that the adjustment does not to exceed the amount of net savings generated by the ACO during the first agreement period due to ACO participant list changes that may increase the number of assigned beneficiaries in the second agreement

period. We will use data from the ACO's finalized financial reconciliation report for the performance year which corresponds to the benchmark year for the second agreement period to calculate the adjustment. The calculation will include the following steps:

- Step 1. Determine whether the ACO generated net savings. For each performance year we will determine an average per capita amount reflecting the quotient of the ACO's total updated benchmark expenditures minus total performance year expenditures divided by performance year assigned beneficiary person years. However, the ACO's total updated benchmark expenditures minus total performance year expenditures may not exceed the performance payment limit for the relevant track. If the sum of the 3 performance year per capita amounts is positive, the ACO would be determined to have net savings and we would proceed with Steps 2 and 3. If the sum of the 3 performance year per capita amounts is zero or negative, we will not make any adjustment to the ACO's rebased benchmark to account for any savings the ACO may have generated under its prior agreement period.

- Step 2. Calculate an average per capita amount of savings reflecting the ACO's final sharing rates based on quality performance. We will average the performance year per capita amounts determined in Step 1 to determine the average per capita amount for the agreement period. We will also determine the ACO's average final sharing rate, based on an average of the ACO's quality performance in each performance year of the agreement period. Therefore, the average per capita amount of savings will account for those situations where an ACO's sharing rate for a performance year is set equal to zero (based on the ACO's failure to meet

the quality performance requirements in that year). We will then calculate an average per capita amount of savings which is the product of the average performance year per capita amount and the average sharing rate based on quality performance.

- Step 3. Add the average per capita amount of savings determined in Step 2 to the ACO's rebased historical benchmark developed following the methodology specified under § 425.602 as modified by this final rule. The additional per capita amount will be applied to the ACO's rebased historical benchmark for a number of assigned beneficiaries (expressed as person years) not to exceed the average number of assigned beneficiaries (expressed as person years) under the ACO's first agreement period. Imposing this limit will help ensure that the adjustment does not exceed the amount of net savings generated by the ACO during the first agreement period due to ACO participant list changes that may increase the number of assigned beneficiaries in the second agreement period.

We are adding a new provision at § 425.602(c)(2)(ii) to reflect this adjustment. We further note that ACOs with April 1, 2012 and July 1, 2012 agreement start dates had a first performance year spanning a 21-month or 18-month period (respectively), concluding December 31, 2013. In calculating the average per capita amount of savings for these ACOs, we will use calendar year 2013 data from the performance year 1 final financial reconciliation for these ACOs, to align with the same 12 month period for the corresponding benchmark year under the new agreement.

To illustrate how this calculation will be performed, take as an example the following hypothetical Track 1 ACO:

TABLE 7—HYPOTHETICAL PERFORMANCE DATA—INCORPORATING SAVINGS INTO REBASED BENCHMARK

	PY1	PY2	PY3	Average
A. Person Years	31,024	32,579	32,463	32,022 (average of A for PY1, PY2, PY3).
B. Total benchmark expenditures minus total expenditures.	\$19,265,778.00	(\$48,470,676.00)	\$21,824,075.00	
C. Per capita total benchmark minus total expenditures (C = B/A).	\$621.00	(\$260.00)	\$672.28	\$344.42 (average of C for PY1, PY2, PY3).
D. Final Sharing Rate	50%	0.0%	40%	30% (average of D for PY1, PY2, PY3).
E. Average per capita amount to add to Rebased Historical Benchmark.	—	—	—	\$103.33 (E = average C * average D).

For this example, it is assumed that the amount of savings or the ACO's total benchmark expenditures minus total expenditures is less than its performance payment limit, equivalent to 10 percent of the ACO's updated historical benchmark in each performance year. It is also assumed that in PY2, the ACO did not meet the quality performance standard and therefore did not qualify to share in any portion of shared savings (*i.e.* final sharing rate equals zero). Under Step 1 of the calculation, we sum the per capita total benchmark minus total expenditure values (\$621, – \$260, \$672.28) to determine whether the value is greater than zero and therefore whether the ACO generated net savings. Under Step 2 of the calculation, we determine the average performance year per capita amounts. In the illustration, this average is \$344.42. We also determine that the ACO's average final sharing rate is 30 percent (50% + 0% + 40% divided by 3). We calculate an average per capita amount of \$103.33 ($\$344.42 * 0.3$) to add to the ACO's rebased historical benchmark. The average per capita amount of \$103.33 would only be applied to the rebased benchmark for a number of assigned beneficiary person years not to exceed 32,022 person years, the average of the ACO's performance year assigned beneficiary person years under its first agreement period.

At this time, we have decided not to adopt a policy under which we would adjust the ACO's rebased benchmark to account for losses generated or shared by ACOs in an earlier agreement period if the sum of the ACO's prior agreement period performance year per capita amounts is zero or negative. Our policy would take into account losses generated during an agreement period by offsetting any savings in determining if there were net savings during the first agreement period. We are particularly concerned about discouraging continued participation in the program by Track 1 ACOs who are making a bona fide effort to meet the program's goals but need more than several years to establish the strategies and operations to be successful in the program. In these cases, an adjustment to account for net losses in the ACOs' rebased benchmarks could make it very difficult for the ACOs to achieve success in their next agreement period. We believe the approach we are adopting in this final rule balances the interests of the Medicare Trust Funds and interests of ACOs entering their second agreement period. In particular, we believe this adjustment will encourage continued

participation by ACOs who have been previously successful in the program by more gradually decreasing their rebased benchmarks in a way that will reflect their previous success in lowering expenditures for assigned beneficiaries while also not discouraging participation by ACOs who did not achieve net savings under their first agreement period. However, we remain concerned about the possibility for unintended benefits to ACOs from the revised rebasing methodology we are adopting in this final rule. We are especially concerned about a situation where a Track 1 ACO generates statistically significant losses in one agreement period which in turn yields a higher benchmark under a subsequent agreement period. Therefore, we intend to carefully evaluate the effects of rebasing on ACOs who have generated losses under a prior agreement period and may revisit this issue in future rulemaking.

Comment: A few commenters addressed the point that incorporating performance year three data into the ACO's benchmark for the following agreement period would delay the availability of the ACO's new benchmark. Several commenters explained that this delay in issuing benchmarks was acceptable because of the need to await financial performance data from the previous agreement period. However, these commenters suggested that a preliminary benchmark excluding the shared savings payments be provided in a timely manner. A commenter expressed concern about the delay in producing the benchmark as CMS calculates the third performance year results. Although the commenter found some merit in the approach of including shared savings in the ACO's benchmark, the commenter placed greater weight on the need for ACOs to receive more timely data to make decisions and changes to impact the three-part aim.

Response: We appreciate commenters' concerns about an ACO's need for timely, actionable data on its benchmark close to the start of the ACO's agreement period. We currently provide ACOs with a preliminary benchmark close to the start of the agreement period for informational purposes. According to our current practice, we will continue to provide an ACO with a preliminary historical benchmark close to the start of the ACO's agreement period. We will issue a final benchmark once complete data are available, including any adjustment for savings in the prior agreement period.

Comment: Some commenters suggested that we implement some

combination of the five alternative benchmarking methodologies discussed in the December 2014 proposed rule. Commenters typically suggested using a combination of equally weighting the three benchmark years and accounting for shared savings payments in benchmarks. Some suggested that, in addition, we use regional FFS expenditures (as opposed to national FFS expenditures) to trend and update the benchmarks, or implement an alternative methodology for resetting ACO benchmarks that would hold an ACO's historical costs constant relative to costs in its region for all of the ACO's subsequent agreement periods, or both. A commenter suggested adopting a combination of equally weighting the three benchmark years and using regional FFS expenditures (as opposed to national FFS expenditures) to trend and update the benchmarks.

A commenter, favoring the approach where we would transition ACOs to benchmarks based only on regional FFS costs, expressed concern that the other alternatives do not align with methods used for updating payments in other Medicare programs, such as Medicare Advantage.

Commenters supporting the modifications under which we would equally weight the three benchmark years and account for shared savings payments in resetting benchmarks often indicated that these changes would protect against creating benchmarks that progressively require ACOs to beat their own best performance.

Response: We appreciate commenters' thoughtful consideration of using a combination of the benchmarking alternatives discussed in the December 2014 proposed rule. We agree with commenters who expressed that accounting for an ACO's shared savings during its prior agreement period taken together with equally weighing the ACO's benchmark years would more gradually lower the benchmarks of ACOs that perform well. This, in turn, could increase the incentive for ACOs to continue to generate shared savings and improve quality because they will not be penalized for this success in future agreement periods. Moreover, these modifications may encourage ACOs to enter the program's two-sided models (such as the new Track 3), which offer higher final sharing rates, because adjusting ACO benchmarks to reflect successful participation during one agreement period may improve the potential for ACOs to receive shared savings in the next agreement period. We believe these modifications will address, in part, stakeholders' concerns regarding sustainability of the model.

Further we consider these modifications to the rebasing methodology important for addressing the immediate issue of how to rebase the benchmarks of ACOs whose second agreement period will begin January 1, 2016.

As explained later in this section, while we are not making broader modifications to the benchmarking methodology in this final rule to set ACO benchmarks based in part on regional FFS costs, we anticipate issuing a proposed rule this summer that would propose more comprehensive revisions to the program's benchmarking methodology. As we further develop these proposals, we will take into account the possible interactions between these alternatives and the modifications to the rebasing methodology to equally weight the benchmark years and account for savings generated in an ACO's prior agreement period that we are adopting in this final rule. Although we believe it is appropriate at this time to finalize a policy for accounting for savings generated by an ACO under its initial agreement period in resetting the ACO's benchmark, applicable to its second agreement period, we believe it will be critical to revisit the policy of accounting for an ACO's savings generated in a prior agreement period when resetting its benchmark in conjunction with any change to the methodology for establishing updating and resetting benchmarks to incorporate regional FFS costs. Accordingly, we plan to carefully evaluate the effects of the policies we are adopting in this final rule and will revisit these policies in the future rulemaking regarding the benchmarking methodology.

FINAL ACTION: We are finalizing revisions to § 425.602(c) to specify that in resetting the historical benchmark for ACOs entering their second agreement period we will make an adjustment to reflect the average per capita amount of savings earned by the ACO in its first agreement period, reflecting the ACO's financial and quality performance, and number of assigned beneficiaries, during that agreement period. The additional per capita amount will be applied to the ACO's rebased historical benchmark for a number of assigned beneficiaries (expressed as person years) not to exceed the average number of assigned beneficiaries (expressed as person years) under the ACO's first agreement period. If an ACO was not determined to have generated net savings in its first agreement period, we will not make any adjustment to the ACO's rebased historical benchmark. We will use performance data from each of the ACO's performance years under its first

agreement period in resetting the ACO's benchmark under its second agreement period. For ACOs with April 1, 2012 and July 1, 2012 agreement start dates that will be entering their second agreement period in 2016, we will use calendar year 2013 data from the performance year 1 final financial reconciliation for these ACOs, to align with the same 12 month period for the corresponding benchmark year in performing this calculation. As we currently do now, we will continue to issue a preliminary benchmark to an ACO, close to the start of the ACO's subsequent agreement period, based on available data. We will then issue a final historical benchmark once we have the data needed to determine the ACO's financial and quality performance for its third performance year under its prior agreement and complete the benchmark calculation as required under §§ 425.602(a) and 425.602(c).

c. Use of Regional Factors in Establishing, Updating and Resetting Benchmarks

As discussed in the December 2014 proposed rule, some stakeholders have expressed concern that the existing benchmarking methodology does not sufficiently account for the influence of cost trends in the surrounding region or local market on the ACO's financial performance and does not suitably encourage ACOs to achieve and maintain savings. Therefore, we discussed and sought comment on several options and methods for incorporating regional factors when establishing, updating, and resetting the benchmark.

First we discussed use of regional FFS expenditures, instead of national FFS expenditures, to trend forward the most recent three years of per beneficiary expenditures for Parts A and B services in order to establish the historical benchmark for each ACO and to update the benchmark during the agreement period. Specifically, we sought comment on an option that would implement an approach similar to the method for updating benchmarks used under the PGP demonstration.

Second, we discussed an approach under which the ACO's benchmark from the prior agreement period would be updated according to trends in FFS costs in the ACO's region, effectively holding a portion of the ACO's reset benchmark constant relative to its region. In the proposed rule, we discussed two options for implementing this methodology:

- Option 1: An ACO's benchmark for its initial agreement period would be set according to an approach similar to the

existing methodology. For subsequent agreement periods, the trend in regional costs would be calculated using an approach based on the PGP demonstration, and the historical benchmark would be updated by increasing it by a percentage equal to the percentage increase in regional costs.

- Option 2: In resetting the benchmark, information regarding the ACO's historical costs relative to its region prior to its first agreement period would be used to develop a scaling factor that would be applied to regional FFS benchmarks for a future agreement period.

Third, we discussed an approach under which, over the course of several agreement periods, we would transition ACOs from benchmarks based on their historical costs toward benchmarks based only on regional FFS costs. Under this approach, ACO benchmarks would gradually become more independent of the ACO's past performance and gradually more dependent on the ACO's success in being more cost efficient relative to its local market.

We also sought comment on a number of technical issues specific to these alternatives, including: How to define an ACO's region and specifically, the ACO's regional reference population; how to account for changes in an ACO's Participant TINs from year-to-year and across agreement periods; and considerations related to risk adjusting benchmarks based on regional factors. We also discussed and sought comment on how broadly or narrowly to apply these alternative benchmarking approaches to the program's Tracks, and the timing for implementing any changes.

We welcomed commenters' detailed suggestions on our considerations of factors to use in resetting ACO benchmarks and for the alternative benchmark methodologies; as well as considerations or concerns not described in the proposed rule. In particular, we sought commenters' input on whether an approach that transitions ACOs to regional benchmarks would encourage continued participation by existing low-cost and high-cost ACOs. We also requested commenters' input on alternatives not described in the proposed rule for resetting benchmarks to encourage ongoing participation by ACOs who perform well in the program and are successful in reducing expenditures for their assigned beneficiaries. We also sought comment on whether these alternative benchmarking approaches would have unintended consequences for ACO participation in the program, for the

Medicare Trust Funds, or for Medicare FFS beneficiaries.

We signaled our intent to carefully review any comments received on these issues during the development of the final rule and to determine whether any change to our current methodology for establishing benchmarks would be necessary and appropriate and would meet relevant statutory requirements under section 1899(d)(1)(B)(ii) and section 1899(i)(3) of the Act.

Comment: Many commenters generally indicated their support for revising the benchmarking methodology to reflect regional cost variation. Some commenters specifically addressed the options discussed in the December 2014 proposed rule about how to incorporate regional costs into ACO benchmarks. Some commenters provided an array of alternative suggestions on how to incorporate regional costs into ACO benchmarks, including options not explicitly discussed in the proposed rule. Others expressed their preference for continuing to implement a benchmarking methodology that establishes ACO-specific benchmarks that account for national FFS trends.

Some commenters generally encouraged CMS to reflect location-specific changes in Medicare payment rates in the benchmarks by using regional factors (based on regional FFS costs) in establishing and updating ACO-specific benchmarks. Others supporting this approach explained that regional expenditures more accurately reflect the health status of populations (for risk adjustment), differences between rural and urban areas or market/regional differences more generally, and differences in beneficiaries' socio-economic status. A commenter who supported use of regional costs in updating benchmarks indicated this would better address the effects of churn in the ACO's assigned population, which the commenter explained leads the ACO's population to become less reflective of its historical population and more reflective of its regional population. On the other hand, some commenters encouraged CMS to continue using factors based on national FFS costs to trend and update benchmarks. For example, a commenter expressed concern that using regional FFS expenditures instead of national FFS expenditures in establishing and updating the benchmark may further disadvantage existing low-cost ACOs. Others supported allowing ACOs a choice of either regional and national trends, or applying the higher of regional or national trends, or applying regional trends to ACOs in existing high-cost regions and national trends to

ACOs in existing low-cost regions. Several commenters offered conflicting views on whether moving to use of regional FFS costs in establishing historical and updated benchmarks would advantage or disadvantage existing low cost providers.

Some commenters supported the option under which we would hold an ACO's historical costs constant relative to its region, or similar approaches. A commenter expressed support for this approach if it meant that the savings in one performance period would not work against the ACO in the next agreement period. Several commenters specifically favored the option discussed in the proposed rule, under which we would use a scaling factor for adjusting the ACO's historical costs under its first agreement period in developing its benchmark for future agreement periods. Several commenters disagreed with this alternative, concerned that this method would: (1) Create a static benchmark based on the organization's historical performance that does not evolve to account for the changing performance or patient mix of the ACO over time, and as a result could create disincentives for the ACO to grow or expand to other locations or communities for fear of attracting a disproportionate prevalence of sick patients (if not reflected in the population used to establish its initial benchmark); (2) fail to account for changes in FFS spending trends that occur over time, as new codes and payment rules are introduced; (3) require additional trending which would create a benchmark methodology that fluctuates greatly depending on the region that is the basis for comparison and make a more complicated benchmarking methodology that is harder to implement, forecast and explain.

Of the options to incorporate regional FFS costs into ACO benchmarks, the option whereby we would transition ACOs to benchmarks based only on regional FFS costs over the course of multiple agreement periods seemed to garner the greatest support from commenters. Several commenters believe that this benchmarking process best recognizes ACOs' concerns about performance relative to other providers in the region, while also encouraging ACOs to continue to improve over time. A commenter further explained that this approach accounts for the halo effect of the ACO in its community, where non-ACO providers in the community have become more efficient due to the presence of an ACO. Commenters offered mixed views about the impact of this approach on existing high- and low-

cost ACOs, with a commenter explaining that an ACO's incentive to participate in the program would depend on whether the ACO's market was determined to be cost efficient or inefficient. Others expressed concerns that this approach would make it difficult for ACOs to add additional ACO participants. Therefore it would slow adoption of the Shared Savings Program because ACOs may be reluctant to risk including new providers with historically higher costs, and it similarly may incentivize ACOs to terminate, rather than remediate, high-cost providers within the ACO.

Commenters expressed the importance of defining the regional comparison group under this alternative for transitioning ACOs to benchmarks based on regional FFS spending, particularly in light of regional variations in payment policies. Several commenters addressing this option suggested that the metric for efficient, cost-effective care should be consistent across providers within a region, including Medicare Advantage plans. A commenter suggested segmenting the benchmark by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) when using regional FFS costs to establish the ACO's benchmark, as is currently done in the program's financial methodology, and making further adjustments for the cost of care of dually eligible and ESRD beneficiaries.

On the topic of the pace for transitioning ACOs to regional benchmarks, commenters' suggestions ranged from rapid transition (within the first agreement period) to a slower pace (for example, over the course of two, three, four, or even five agreement periods). Several commenters suggested a different pace of transition depending on the ACO's historical costs relative to its market, recommending a slower transition for higher costs ACOs and a faster transition for lower cost ACOs. Others suggested a different pace for transitioning more or less experienced ACOs, or an approach under which an ACO could determine its own pace of transitioning to a regional benchmark. A commenter indicated this approach should initially be implemented under the two-sided payment models, but that all ACOs should be transitioned to regional FFS benchmarks by year 2021.

Commenters addressing the three options for incorporating regional costs into benchmarks often pointed to the importance of the definition of the ACO's region to the credibility of these benchmarking methodologies. Several commenters supported a methodology for defining an ACO's region and ACO-

specific regional FFS costs that would be similar to the approach used in the Physician Group Practice (PGP) demonstration as described in the proposed rule. Others suggested alternatives including using Medicare Advantage (MA) county-level FFS rates, or using Hospital Referral Region (HRR) geographies weighted by beneficiary residence, or Metropolitan Statistical Areas (MSAs). Commenters also offered detailed suggestions on how to define an ACO's reference population, with a fairly even split between those commenters that favored including and excluding an ACO's assigned beneficiaries. Others offered considerations for selecting an ACO's counties and for defining its reference population, relative to where assigned or attested beneficiaries reside or receive services. Others stressed the importance of a sufficiently large reference population, offering suggestions on how to expand the ACO's region if needed. Some commenters pointed out the importance of regional comparisons due to the variation in local rules and regulations as they pertain to FFS payment, and variation in the socio-economic status of beneficiaries (particularly dually eligible beneficiaries). A commenter explained that under an approach like that used for the PGP demonstration, an ACO could become a winner or loser under the program based in large part on the comparison group, which reflects how other providers in the region are performing. Moreover, for a voluntary program like the Shared Savings Program, organizations may choose to participate simply because their costs are lower than those of the region, potentially leading to significant increases in Medicare costs without improvements in quality.

Few commenters addressed concerns about accounting for ACO Participant List changes under the alternative benchmarking methodologies discussed in the December 2014 proposed rule. Several commenters favored an approach under which we would adjust the ACO's benchmark each performance year as ACO participants are added or removed, and a commenter suggested we account for changes in the health status or disease burden of the ACO's assigned beneficiary population arising from the changes in the ACO Participant List. A commenter further recommended a more fluid approach under which the benchmark would be risk adjusted based on changes in the assignment of individual beneficiaries.

Some commenters addressed the need to revise the program's risk adjustment methodology when moving to an

alternative benchmarking methodology. Commenters suggested, for instance: Using a regional HCC growth rate or accounting for regional variation in updating the HCC formulas; using a concurrent risk adjustment methodology, and doing so in combination with a demographically adjusted regional FFS cost baseline; creating a risk adjustment factor by comparing the HCC coding between the ACO assigned beneficiaries and the regional comparison population; following the Medicare Advantage (MA) methodology for risk adjustment; and readjusting the risk determination of a population after removing beneficiaries determined ineligible for assignment. Some suggested that CMS not be overly restrictive in applying regional normalization and coding intensity adjustments. Others suggested CMS specifically account for other factors in regional adjustments such as changes in access to care for low-cost populations, and the socio-economic risk profile of beneficiaries. A commenter requested that risk adjustment be based on the ACO's historical performance and not the market's historical performance.

Although the December 2014 proposed rule did not explicitly request comment on the program's existing risk adjustment methodology, many commenters took the opportunity to criticize this aspect of the calculation of ACO benchmarks. Almost all commenters addressing the program's existing risk adjustment methodology suggested that it inadequately captures the risk and cost associated with assigned beneficiaries. Commenters explained their concern that by only counting HCC scores that work against the ACO for the continuously enrolled population, the current policy actually disadvantages ACOs that take on the management of the sickest populations with the greatest medical need. Of the alternatives to the current risk adjustment methodology presented by commenters, many commenters urged CMS to incorporate the full growth in HCC risk scores across each performance year (upward and downward adjustment), or, at a minimum, to recognize the full growth in risk scores for beneficiaries in their first year of assignment to the ACO. In justifying this alternative, commenters suggested that ACOs are less susceptible to coding practices, for instance compared to MA plans, because ACOs can be comprised of entities with no influence over the coding practices at other facilities or settings. Others suggested accounting for full risk score growth could address CMS' concerns

about providers' avoidance of at-risk beneficiaries. Some commenters explained that failing to fully adjust for changes in beneficiary health status ignores the fact that even when care is optimally managed, individuals become sicker. Therefore, a beneficiary is more expensive to treat as disease processes progress or when they initially present. Some commenters indicated that the program's current risk adjustment methodology requires vigilant ongoing coding of chronic conditions to prevent a decline in risk scores. Others recommended approaches under which CMS would encourage improved coding practices by providers (for example, rural providers). Other commenters envisioned that a better approach would involve more frequent risk adjustment (for example, quarterly), use of different risk scores (for example, concurrent performance year risk scores, or regionally-based risk factors, or projected risk based on expected cost of beneficiary care), or allow for ACOs to send in supplemental risk score data as is done under Medicare Advantage. Others suggested that CMS' concerns about upcoding could be addressed through vigilant monitoring or placing a cap on upward risk adjustment growth (for example, relative to a national or regional growth rate). A commenter indicated the importance of incorporating national FFS payment changes in the risk adjustment methodology. Some urged CMS to continue researching alternative risk adjustment models and consider additional changes to increase the accuracy of the risk adjustment methodology.

Commenters suggested CMS consider a variety of additional methodologies for revising the program's benchmarks, sometimes creating opposing alternatives. MedPAC offered a vision for both the near and long term evolution of the program's benchmarking methodology. In the short term, CMS would keep the existing rebasing methodology, but would not rebase an ACO that met a two-part test, which would leave benchmarks for lower-spending ACOs unchanged. In the longer term, CMS would move ACOs from a benchmark based on the ACO's historical cost experience to a common (equitable), local FFS-based benchmark where: FFS spending is defined to include spending on beneficiaries in ACOs as well as on beneficiaries in traditional FFS; the risk adjustment methodology reflects expected increases in costliness of the beneficiary's care and protects against coding differences; and better quality performance is

rewarded with a higher benchmark (a bonus-only model). MedPAC encouraged CMS to focus on creating the conditions that will allow efficient ACOs to be successful, rather than establishing an environment which creates as many ACOs as possible. Other commenters suggested the following alternatives:

- Less frequent rebasing. For instance, carry forward the ACO's first agreement period benchmark into subsequent agreement periods. That is, do not reset or update this benchmark, or alternatively, trend forward the first agreement period benchmark in subsequent agreement periods. Some commenters suggested limited rebasing, or alternative rebasing for low-cost ACOs. Other commenters asked whether CMS could establish a benchmark floor, an actuarial number beyond which CMS would not lower an ACO's benchmark.
- More frequent rebasing. For instance, reset the ACO's benchmark annually during each year of the agreement period.
- Annually increase the ACO's benchmark using a region-specific consumer price index (CPI).
- Measure ACO performance against a national baseline, considering also the ACO's own past performance and the ACO's performance relative to others in its market.
- Reward low-cost providers for improvement in performance regardless of their performance compared to the national or local trend.
- Apply to each ACO a benchmark which is the higher of either a benchmark based on the ACO's historical costs or a benchmark based on regional costs. Alternatively, a commenter suggested rewarding ACOs that beat either of two benchmarks, one based on the ACO's historical cost experience and one based on the ACO's regional costs.
- Adopt the Medicare Advantage methodology for paying plans based on a monthly per capita county rate in creating ACO benchmarks, particularly for ACOs in low cost counties. Specifically for ACOs in the lowest quartile of costs, apply a benchmark that is 115 percent of estimated FFS costs, and allow for double bonuses if quality benchmarks are achieved.
- Adopt an alternative benchmarking methodology for ACOs under prospective assignment. For example, the benchmark could be based on the historical costs of the specific beneficiaries that are assigned to the ACO for a performance year, rather than on the average costs of the ACO's historical patient population.

- Revise the approach to trending and updating the ACO's benchmark. Several commenters suggested segmenting and adjusting the benchmark by service mix (e.g., expenditures by differing care settings), similar to the current approach for segmenting the benchmark by Medicare enrollment type. Another commenter suggested using actual trend data, as opposed to estimated (projected) trend data to establish and update the benchmark. A commenter suggested eliminating the benchmark update altogether.

- Address the effects of beneficiary churn on benchmarks, for instance by using additional historical data in establishing benchmarks or locking-in an ACO's assigned beneficiaries for multiple years.
- Normalize random fluctuations in FFS cost estimates for the ACO's assigned beneficiary population.
- Revisit the MSR calculation under Track 1 if moving to regional benchmarks, to see if the MSR could be lowered.

Some commenters supported blended approaches, whereby benchmarks would reflect a combination of the ACO's historical costs and regional, national or a combination of regional/national costs. For instance, a benchmark based on the ACO's historical costs and: (1) Only national FFS trend factors (as is currently done); (2) only regional FFS trend factors; or (3) a combination of both regional and national FFS trend factors. Others suggested that an ACO's benchmark be comprised of a blend of the costs for the ACO's assigned beneficiaries (historical costs) and either regional costs or regional/national costs. A few commenters addressed the weight regional and national costs should be given in relation to the ACO's historical costs in these blended approaches, and especially in the context of discussing the pace for transitioning ACOs to benchmarks based only on regional costs. Some commenters favored options that would allow ACOs (particularly those under the two-sided model) a choice of benchmarking methodology, such as benchmarks reflecting national FFS costs versus those reflective of regional costs.

Commenters offered differing suggestions on whether to broadly or narrowly apply a benchmarking methodology that accounts for regional costs across the program's tracks. Some commenters favored applying the same benchmarking methodology across program tracks, particularly to provide consistency in methodology as ACOs move between tracks (namely from Track 1 into a two-sided risk track).

Others suggested using an alternative benchmarking methodology to create distinctions between the tracks, for instance applying the changes only in Tracks 2 and 3 to attract ACOs to performance-based risk. Some others recommended allowing ACOs under the two-sided model a choice of multiple benchmarking methodologies, including at least one option that accounts for regional costs, while other commenters suggested giving all ACOs this choice. If CMS adopts a revision to the benchmarking methodology, a commenter recommended that the changes become effective for all ACOs beginning with the first full performance year after the final rule is published.

Some commenters explained it would be premature for CMS to finalize any benchmarking changes at this time. Some commenters indicated there were insufficient details in the December 2014 proposed rule on the alternatives or cited their lack of data to analyze the alternatives discussed in order to make an informed and effective recommendation about the options. In particular, commenters pointed to the need for more details on the following:

- Definition of an ACO's region.
- Regional FFS data that would be used in incorporating regional factors into the benchmarking methodology.
- Risk adjustment.
- Adjustments for changes in ACO Participant TINs.
- Impact of these approaches on existing high and low cost providers as well as on existing ACOs according to their past performance in the program (for example, the potential impact of these changes on ACOs who have generated savings or losses).
- Disincentives for ACOs to include providers who manage the highest risk populations under a revised benchmarking methodology.
- Impact of regional or comparison population-based benchmarks on ACOs that include certain providers, such as critical access hospitals (CAHs) or academic medical centers.
- Budget neutrality of a revised benchmarking approach.

These commenters typically indicated the need for CMS to perform additional modeling and analytic work on the alternatives discussed in the proposed rule, and specifically the aforementioned issues. They urged CMS to share the results of this analysis and put forward detailed proposals on revisions to the benchmarking methodology through additional notice and comment rulemaking. A commenter further suggested that CMS convene a task force of CMS and ACO

representatives to evaluate and recommend benchmarking alternatives.

Response: We believe that the changes to the benchmark rebasing methodology we are finalizing in this final rule—equally weighting the benchmark years and accounting for savings generated in the ACO's first agreement period—will help to ensure that the Shared Savings Program remains attractive to ACOs, provides strong incentives for ACOs to improve the efficiency and quality of patient care, and generates savings for the Medicare Trust Funds. However, as we discussed in the December 2014 rule and as highlighted by many commenters, we continue to believe that additional changes to benchmark rebasing methodology are needed in order to ensure that the Shared Savings Program meets these goals over the long run. We agree with stakeholders that developing a benchmark rebasing methodology that incorporates regional cost factors into benchmarks is an important consideration in the development of the program, including for ensuring the sustained attractiveness of the program and for encouraging ACOs to achieve and maintain savings. In particular we believe that three main criteria should be used to evaluate a revised benchmarking methodology. Such a methodology should generate the following:

- Strong incentives for ACOs to improve efficiency and to continue participation in the program over the long term.
- Benchmarks which are sufficiently high to encourage ACOs to continue to meet the three-part aim, while also safeguarding the Medicare Trust Funds against the possibility that ACOs' reset benchmarks become overly inflated to the point where ACOs need to do little to maintain or change their care practices to generate savings.
- Generate benchmarks that reflect ACOs' actual costs in order to avoid potential selective participation by (and excessive shared payments to) ACOs with high benchmarks. In general, we believe that benchmarking approaches involve tradeoffs among these three criteria.

We believe that the current benchmark rebasing methodology does not achieve the best possible tradeoff among these criteria. While we believe that the modifications to the rebasing methodology we are finalizing in this final rule—equally weighting the benchmark years and accounting for savings generated in the ACO's first agreement period—will improve the extent to which the program's benchmarking methodology meets these criteria, we believe additional changes

to the benchmark rebasing methodology are needed in order to ensure these goals are met over the long run.

However, we believe that the alternatives discussed in the December 2014 proposed rule, including an approach which would have based ACOs' future benchmarks entirely on regional FFS costs in the regions served by the ACO, may not strike the best balance among the considerations identified above. For instance, under approaches where an ACO's benchmark is no longer based directly on the ACO's own recent costs, the benchmark would less accurately match the ACO's underlying costs and increase the risk of selective participation. Therefore, we intend to propose a benchmarking methodology based on a blend of each ACO's recent cost experience and cost trends in its region. We intend to propose revisions to the program's benchmark rebasing methodology in a rule to be issued later this summer, as described in greater detail under the Final Action later in this section. While we received comments supporting quick adoption of changes to the benchmarking rebasing methodology to account for regional FFS costs, we are concerned that adopting changes in this final rule would provide short notice to ACOs that must determine whether to enter a second agreement period starting on January 1, 2016. For this reason we intend to propose that the revised benchmark rebasing methodology incorporating the ACO's historical costs and regional FFS costs and trends would apply to ACOs beginning new agreement periods in 2017 or later. ACOs beginning a new agreement period in 2016 would convert to the revised methodology at the start of their third agreement period in 2019.

We appreciate the comments and suggestions from stakeholders on the benchmarking alternatives discussed in the December 2014 proposed rule, and the specific suggestions on risk adjustment, reference population and service area definitions, how broadly or narrowly to incorporate an alternative benchmarking methodology into the program and the pace at which to make these changes, considerations related to ACO Participant List changes, and other factors that would need to be developed prior to adopting a benchmarking methodology that includes regional FFS costs. We recognize stakeholders' interest in participating in the development of policies for revising the benchmarking methodology, and in particular the importance of stakeholder feedback in considering the potential effects of, and unintended consequences resulting from, revisions to the

benchmarking methodology. We will take the comments and suggestions we received in response to the discussion in the proposed rule into consideration when evaluating and developing the forthcoming policy proposals on an alternative benchmarking model.

Some of the suggestions commenters provided related to revising the program's benchmarking methodology are beyond the scope of the modifications proposed or sought comment on in December 2014 proposed rule, including suggestions for revising the program's existing risk adjustment methodology. We have limited experience with how this methodology affects ACO financial experience or influences the coding practices of ACOs, ACO participants and ACO providers/suppliers since at the time of this final rule we have final financial reconciliation results for only 1 performance year, for ACOs with 2012 and 2013 agreement start dates. As suggested by some commenters, we will continue to evaluate the current risk adjustment methodology. We will also continue to monitor the concerns raised by commenters about the possible effects of the existing risk adjustment methodology, including its impact on ACO financial performance, providers' coding practices and care for beneficiaries. Although at this time we believe revising the existing risk adjustment methodology is premature, we will continue to evaluate this issue, and will address any necessary refinements to the risk adjustment methodology in the forthcoming policy proposals on a benchmark rebasing model that incorporates regional FFS costs. In particular, we anticipate addressing the need for a risk adjustment methodology to account for coding differences between the ACO and its region.

FINAL ACTION: As described in section II.F.5.b. of this final rule, we are finalizing modifications to the benchmark rebasing methodology, to include equally weighting the ACO's historical benchmark years, and accounting for savings generated in the ACO's first agreement period when setting the ACO's benchmark for its second agreement period. Recognizing the importance of quickly moving to a benchmark rebasing approach that accounts for regional FFS costs and trends in addition to the ACO's historical costs and trends, we intend to propose and seek comment on the components of and procedures for calculating a regionally-trended rebased benchmark through a proposed rule to be issued later this summer. While the forthcoming proposed rule will provide

details of our considerations and preferred methodology, we believe it is important to signal our anticipated policy direction in this final rule. In particular, we anticipate this approach would include the following features:

- Continue to establish the ACO's historical benchmark for its first agreement period by calculating a historical benchmark based on the three most recent years prior to the start of the ACO's agreement period. We intend to discuss in the forthcoming proposed rule whether the appropriate weighting under the revised methodology is weighting the three benchmark years equally or following the current methodology of weighting at 10 percent for benchmark year (BY) 1, 30 percent for BY2, and 60 percent for BY3.

- For an ACO's second or subsequent agreement period, the benchmark would be rebased as a blend of a regionally-trended component and a rebased component, for instance—

++ *Regionally-trended component:* The ACO's historical costs calculated from the historical benchmark years for the 3 years preceding the ACO's first agreement period that starts in 2017 or later, adjusted by a regional trend factor based on changes in regional expenditures for each Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) for the most recent year prior to the start of the ACO's new agreement period, adjusted for changes in the health status and demographic factors of the population in each benchmark year relative to its region. The ACO's region would be defined relative to the areas where its assigned beneficiaries reside, for instance by using MSAs and regions constituting the non-MSA portions of the state; and

++ *Rebased component:* The ACO's recent historical expenditures, determined by calculating a historical benchmark according to the rebasing methodology established with this final rule—based on the 3 most recent years prior to the start of the ACO's new agreement period—including equally weighting these benchmark years but excluding the addition of a portion of savings generated over the same 3 most recent years.

An important consideration is the percentage each component accounts for in the rebased benchmark. We believe that placing a 70 percent weight on the regionally-trended component and a 30 percent weight on the rebased component would serve the goal of providing strong incentives for ACOs to achieve savings and to continue to participate in the Shared Savings Program. Further, we anticipate

maintaining our existing policy for adjusting the ACO's historical benchmark whereby we annually account for changes to the ACO's participant list, based on the ACO participant list the ACO certifies before the start of the performance year for which these changes are effective. Specifically, changes in the ACO's certified participant list would result in a recalculation of both the regionally-trended component and rebased component of the ACO's benchmark.

We anticipate that the revised rebasing methodology would be used for the first time to set benchmarks for ACOs beginning new agreement periods in 2017. ACOs beginning new agreement periods in 2016 would convert to the revised methodology at the beginning of their next agreement period in 2019.

In the forthcoming proposed rule later this summer we will put forward details on this approach and address the following issues:

- Whether to make adjustments to account for ACOs whose costs are relatively high or low in relation to FFS trends in their region or the nation, such as specifying a smaller benchmark adjustment for high-spending ACOs.

- The percentage weight of the regionally-trended component and the rebased component, for instance 70 percent and 30 percent respectively; and whether to gradually reduce the weight placed on the regionally-trended component and reallocate this weight to a component based on regional average spending to transition ACOs to benchmarks based on regional FFS costs.

- How to refine the risk adjustment methodology to account for differences in the mix of beneficiaries assigned to the ACO and in the ACO's region; and how we might guard against excessive payments as ACOs improve documentation and coding of beneficiary conditions, such as by adjusting ACOs' risk scores for coding intensity or imposing limits on the extent to which an ACO's risk score can rise relative to its region.

- How to define an ACO's region, including considerations for using MSAs and rest of state designations, or Combined Statistical Areas (CSAs), or another definition of regionally-based statistical areas, or the ACO's county-level service area.

- How to account for changes in ACO Participant composition; for instance, similar to our existing method for adjusting the ACO's benchmark during the course of its agreement period to account for changes in its ACO participant list as described previously.

- Whether to incorporate regional FFS costs in updating an ACO's historical benchmark each performance year, or to maintain the current policy under which we update an ACO's benchmark based on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original fee-for-service program. For instance, the update factor could be based on either regional costs or a blend of regional/national FFS costs, as well as continuing to account for changes during the performance period in health status and demographic factors of the ACO's assigned beneficiaries.

- How to safeguard against rewarding ACOs that increase their spending between now and the beginning of their next agreement period in order to lock in a higher benchmark for future agreement periods.

- How the revised benchmark rebasing methodology using ACO and regional cost trends fits in with the existing approach for establishing the ACO's historical benchmark for its first agreement period and the modifications to the rebasing methodology finalized in this final rule. We will consider whether additional adjustment is needed to transition ACOs to the revised rebasing methodology when they have been previously rebased under the methodology established with this final rule.

6. Technical Adjustments to the Benchmark and Performance Year Expenditures

When computing average per capita Medicare expenditures for an ACO during both the benchmark period and performance years under §§ 425.602, 425.604, and 425.606, we take into account all Parts A and B expenditures, including payments made under a demonstration, pilot or time limited program, with the exception of IME and DSH adjustments, which are excluded from these calculations. In the November 2011 final rule (76 FR 67919 through 67923), we considered whether to make adjustments to benchmark and performance year expenditures to exclude certain adjustments to Part A and B expenditures, including IME and DSH payments, geographic payment adjustments and some bonus payments and penalties. In the final rule, we acknowledged that taking into consideration payment changes could affect ACOs' financial performance and their ability to realize savings. However, with the exception of the adjustment to account for IME and DSH payments, we ultimately declined to make any adjustments to account for various

differences in payment rates among providers and suppliers.

While we exclude IME and DSH payments from the ACO's benchmark under our authority in section 1899(d)(1)(B)(ii) of the Act to make adjustment to the benchmark for such other factors as the Secretary determine appropriate, in order to make a similar exclusion from ACO performance year expenditures we must use our authority under section 1899(i)(3) of the Act. In the November 2011 final rule (76 FR 67921 through 67922), we stated that we believe excluding IME and DSH payments would be consistent with the requirements under section 1899(i)(3) of the Act. That is, excluding these payments from performance year expenditures would both improve the care for beneficiaries while also not resulting in greater payments to ACOs than would otherwise have been made if these payments were included. Specifically, we stated that removing IME and DSH payments from benchmark and performance year expenditures would allow us to more accurately reward actual decreases in unnecessary utilization of healthcare services, rather than decreases arising from changes in referral patterns. In addition, excluding these payments from our financial calculations would help to ensure participation in ACOs by hospitals that receive these payments. Taken in combination, these factors could result in Medicare beneficiaries receiving higher quality, better coordinated, and more cost-efficient care. As a result, we did not expect that excluding IME and DSH payments from the determination of ACOs' financial performance would result in greater payments to ACOs than would otherwise have been made. We also found that excluding these amounts was operationally feasible since they are included in separate fields on claims allowing them to be more easily excluded from financial calculations than certain other payments that are included on Part A and B claims. Therefore, we finalized a policy of excluding IME and DSH payments from both the benchmark and performance year expenditure calculations. We stated that we intended to monitor this issue and would revisit it if we determine that excluding these payments has resulted in additional program expenditures (76 FR 67922).

In addition to IME and DSH payments, we also considered whether standardizing payments to account for other types of payment adjustments would alleviate concerns resulting from changes in the Medicare payment systems. However, in light of the

numerous payment adjustments included throughout the Medicare payment systems, we were concerned about the complexity resulting from standardizing payments and whether standardized payment information would provide meaningful and consistent feedback regarding ACO performance. Ultimately, we disagreed with commenters' suggestions that we adjust expenditures to account for various differences in cost and payment. We stated that making such extensive adjustments, or allowing for benchmark adjustments on a case-by-case basis, would create an inaccurate and inconsistent picture of ACO spending and may limit innovations in ACOs' redesign of care processes or cost reduction strategies (76 FR 67920).

Since the publication of the November 2011 final rule, some questions have persisted regarding the most appropriate way to handle payment differences and changes under Medicare FFS, including whether to take into consideration certain payment changes that could affect ACO financial performance. We did not propose to make any further adjustments to existing program policies in the December 2014 proposed rule, but we did seek further comment from stakeholders on the adjustment for IME and DSH payments and our decision not to make adjustments for other claims-based and non-claims based payments. In particular, we expressed our interest in comments regarding standardization of payments, including which elements to adjust for, the impact of value-based payment adjustments on payments to physicians and hospitals, and the value of providing feedback on non-standardized results while using standardized results to perform financial reconciliation.

Comment: Some commenters reiterated their support for the current program policy to exclude IME and DSH payments from ACO benchmark and performance year expenditures, but not to exclude other payments. A commenter explained that under the current policy ACOs are evaluated against their own previous period performance, and that any standardization or adjustment of expenditures is likely to limit the effectiveness of the program overall. The commenter further indicated that trying to account for one-time or intermittent payment adjustments may overcomplicate the program's financial calculations.

Many commenters favored removing the effect of all policy adjustments from benchmark and performance year expenditures, resulting in cost

standardization for add-on payments and geographic payment differences. Commenters explained that this adjustment is necessary to reflect only actual resource utilization. Commenters explained their concern that absent these adjustments, financial calculations could reward ACOs for simply changing the setting of care, undermine certain types of providers, and place patients at risk for being steered away from appropriate, high-quality care.

Commenters recommended that we make the following adjustments:

- Remove adjustments associated with Medicare value-based payment programs such as the hospital value-based purchasing program (HVBP) and the hospital readmissions reduction program, and the physician value modifier. However, a commenter suggested that CMS further consider the impact of value-based payment adjustments on ACO benchmarks and financial reconciliation.

- Standardize rural payments. Several commenters suggested that CMS normalize cost-based payments to an average prospective payment system rate for calculations in all value programs, while a commenter suggested that medical expenses of rural physicians practicing in a geographic health professional shortage area be normalized to the Medicare FFS rate. Further, several commenters suggested that all special rural payments should be excluded from ACO benchmark and performance year expenditures, with a commenter itemizing these payments: Sole community hospital add-on, inpatient rehabilitation hospital add-ons, psychiatric hospital add-ons, ESRD low volume adjustment, frontier state hospital wage index floor, additional telehealth payments, floor on work geographic practice cost index (GPCI) and practice expense limits, hospital low volume adjustment, Medicare dependent hospital add-on, home health add-on and outpatient hold harmless payments.

- Exclude new technology payments under the Inpatient Prospective Payment System and pass through payment expenditures under the Outpatient Prospective Payment System. Commenters believe exclusion of these payments would avoid incentives for ACOs to underuse new technologies and therapies. Several commenters pointed to the exclusion of an IPPS new technology add-on payment from the spending total for an episode of care under the Bundled Payments for Care Improvement (BPCI) initiative as evidence of the need for these adjustments. Several commenters explained the need for CMS to monitor

patient access to innovative treatments. A commenter pointed to the need for additional patient protections against care stinting by providers pointing to analysis indicating an increase in the utilization of a lower cost procedure option and a decrease in utilization of a higher cost alternative procedure for patients served by ACOs. Several commenters noted CMS' role in fostering development of new technologies, with a commenter pointing to these exclusions as a means to encourage future development of life saving cancer treatments, and another commenter suggesting CMS incent ACOs to participate in clinical trials. Several commenters further pointed to the need for the program's quality measures and quality performance scoring to be more responsive to and better reward adoption of new technologies and treatments. A few commenters further suggested that CMS adopt a process whereby stakeholders would identify breakthrough technologies and treatments for payment or quality measurement adjustments.

- Modify the program regulations to include IME and DSH payments in the calculation of both benchmark and performance year expenditures. A commenter suggested that ACOs have the option to include or exclude IME and DSH payments, explaining that this flexibility would be crucial to address the unique circumstances faced by ACOs, relative to their assigned population and the care facilities within their service area.

Several comments reflected commenters' misunderstanding about the current methodology for calculating ACO benchmark and performance year expenditures by suggesting that we begin to exclude certain payments that fall outside of Part A and B claims in our calculations, including those payments we currently exclude. For example a commenter suggested we exclude direct graduate medical education (DGME) payments and EHR incentive payments for hospitals.

A commenter more generally explained the need for there to be direct correspondence between the benchmark and performance year expenditures to make sure that ACOs are assessed on true performance rather than on changes in payment methodology. However, a commenter suggested the need to allow for upward adjustments to ACO benchmarks in limited situations where significant statutory changes to Medicare payment policies are enacted.

Some commenters suggested other adjustments, including, for example, an

adjustment to account for the transition from ICD-9 to ICD-10.

Response: We appreciate commenters' feedback about technical adjustments to benchmark and performance year expenditures. We agree with commenters who expressed support for the program's existing policies on these issues. We continue to believe that removing IME and DSH payments from benchmark and performance year expenditures allows us to more accurately reward actual decreases in unnecessary utilization of healthcare services, rather than decreases arising from changes in referral patterns. Therefore, we decline at this time to modify our existing policies, which exclude IME and DSH payments from benchmark and performance year expenditures. Further, we will continue to exclude payments that fall outside of Part A and B claims in calculating the benchmark and performance year expenditures, including, for example, DGME payments. We will also continue to take into account individual beneficiary identifiable payments made under a demonstration, pilot, or time limited program when calculating benchmark and performance year expenditures.

At this time, we are not persuaded by commenters' suggestions on the need to further adjust expenditures to account for various differences in cost and payment. We continue to believe that making extensive adjustments to remove the effect of all policy adjustments from benchmark and performance year expenditures, or allowing for expenditure adjustments on a case-by-case basis, would create an inaccurate and inconsistent picture of ACO spending and may limit innovations in ACOs' redesign of care processes or cost reduction strategies (see 76 FR 67920). Unlike the adjustments for IME and DSH payments, we continue to believe that the other payment adjustments that are made to Part A and B payments (such as geographic payment adjustments) do not result in a significant incentive to steer patients away from particular hospitals or providers since an ACO's financial performance would be compared to its own historical expenditure benchmark, as updated. Further, we believe it is important to look to lessons learned from Innovation Center initiatives, particularly the BPCI Model and other ACO models. The recently announced Next Generation ACO Model includes flexibility under the benchmarking methodology to adjust for legislative and regulatory changes enacted during the performance year which have a meaningful impact on expenditures. We

will consider modifying program policies as lessons emerge from the Innovation Center initiatives. We intend to continue evaluating the need for technical adjustments to benchmark and performance year expenditures and may address these issues in future rulemaking.

Comment: Several commenters encouraged CMS to hold ACOs accountable for their assigned beneficiaries' Part D costs. Commenters urged CMS to make sure that all risk-bearing entities in the Medicare program compete on a level playing field, with commenters specifically recommending that CMS foster coordination between Part D plans and ACOs. Because ACOs are not at risk for Part D spending, there is little incentive for them to efficiently manage Part D prescription drug benefits for their enrollees, which could result in cost shifting from Medicare Part B to Part D plans. In contrast, MA-PDs and PDPs bear significant financial risk. To ensure that incentives are properly aligned, commenters recommend: (1) CMS should develop a Part D attribution payment model that rewards ACOs and Part D sponsors for savings generated in Part D; (2) the Part D Medical Loss Ratio rule should be revised to treat activities related to improving care and reducing costs for beneficiaries assigned to ACOs in the Shared Savings Program as quality improving activities; and (3) CMS should establish a process that allows interested parties to request that specific Part B drugs and their administration costs be excluded from the calculation of ACO expenditures. A commenter indicated the need for pharmacy network adequacy, particularly by risk-bearing ACOs.

Response: As we explained in the November 2011 final rule, we do not believe it is appropriate to consider Part D spending in our calculation of benchmark and performance year expenditures. The statute is clear in requiring that we take into account only payments made from the Medicare Trust Funds for Parts A and B services for assigned Medicare FFS beneficiaries, when computing average per capita Medicare expenditures under the ACO. Although commenters pointed out important concerns about the potential for inappropriate cost shifting to Part D, we continue to believe that the program's quality measurement and program monitoring activities will help us to prevent and detect any avoidance of at-risk beneficiaries or inappropriate cost shifting. Furthermore to the extent that lower cost drug therapies available under Part D are not the most appropriate course of treatment and lead

to subsequent visits or hospitalizations payable under Parts A and B, then any costs associated with not choosing the most appropriate treatment for the patient would be reflected in the ACO's per capita expenditures (76 FR 67920).

Comment: Some commenters suggested technical changes to how CMS calculates ACO costs. Several commenters recommended that actual ACO expenditures be based upon dates of service which end during the performance year (rather than begin during the performance year) to achieve the following objectives:

- More timely settlements by having a reduced run-out period.
- More accurate and reliable settlements since CMS uses a national average completion factor of 1.013 for all ACOs based on a 3-month run-out period.

The commenter explained that by calculating based on service end dates, a much lower completion factor would be necessary.

Several commenters provided alternative suggestions on how CMS truncates beneficiary costs under the Shared Savings Program. Several commenters expressed concern that the program's existing methodology for truncating beneficiary costs at the 99th percentile of national FFS is not sufficient protection for smaller ACOs specifically, and generally an insufficient incentive for ACOs to manage the costliest beneficiaries. Alternatively, commenters suggested CMS provide ACOs with several options of outlier caps to choose from based on their size, experience and preference. A commenter suggested the program's existing truncation methodology, where there is a separate threshold for each Medicare enrollment type, creates confusion for ACOs and is also a barrier for managing high-expenditure enrollees as ACOs may decide to not invest scarce resources in controlling costs where they will be unable to make an impact on the three-part aim. Alternatively, this commenter suggested CMS explore using a single, prospectively fixed, dollar cap for the Disabled, Aged/Dual, Aged/Non-Dual categories, but maintain a separate cap for the ESRD category. Another commenter suggested CMS exclude from benchmark calculations beneficiaries who received transplants, those with ESRD, and those with Medicaid long-stay nursing home expenses, and those with a single acute episode costing more than \$100,000 in a year.

Response: The suggestions for technical adjustments to the program's benchmark and performance calculations are beyond the scope of the

December 2014 proposed rule. We appreciate commenters' thoughtful input on these issues. However, we decline at this time to amend these policies through this final rule, and will continue to consider these issues for future rulemaking and policy development.

FINAL ACTION: We are not making additional technical adjustments to our current policy on calculation of benchmark and performance year expenditures, which takes account of all Parts A and B expenditures (including payments made under a demonstration, pilot or time limited program) with the exception of the adjustments for IME and DSH payments, as specified under §§ 425.602, 425.604, 425.606 and the newly established 425.610. However, we intend to continue to evaluate these issues and may revisit them in future rulemaking.

7. Ways To Encourage ACO Participation in Performance-Based Risk Arrangements

Under the current Medicare FFS system, providers have a financial incentive to increase their volume of services. As a result, many current Medicare regulations are designed to prevent overuse of services and the resulting increase in Medicare spending in this context. However, stakeholders such as MedPAC believe that moving ACOs to two-sided performance-based risk under the Shared Savings Program would provide strong incentives for organizations to control costs, which should, in turn, open up the opportunity for regulatory relief across a broad range of issues. Removing certain regulatory requirements may provide ACOs with additional flexibility to innovate further, which could in turn lead to even greater cost savings. These views are supported by analyses performed by CMS actuaries that suggest two-sided performance-based risk provides stronger incentives for ACOs to achieve savings. Thus, ACOs and MedPAC have encouraged us to consider relaxing certain specific FFS Medicare payment and other rules under two-sided performance based risk models in the Shared Savings Program.

Therefore, as discussed in detail in the proposed rule (79 FR 72815 through 72831) we considered what additional flexibilities could be offered to encourage ACO participation in performance-based risk arrangements, including waiving certain Medicare Program rules using our waiver authority under section 1899(f) of the Act, which permits the Secretary to waive "such requirements of . . . title XVIII of this Act as may be necessary to

carry out the provisions of this section." In order to waive FFS payment or other program rules, the waiver must be determined to be necessary for CMS to carry out the provisions of section 1899 of the Act, which governs the Shared Savings Program. In the proposed rule we stated that given the very limited ACO interest thus far in two-sided performance-based risk (to date only 5 of the ACOs participating in the Shared Savings Program have elected to participate under Track 2) and the comments and suggestions by stakeholders, we now believe that using the authority under section 1899(f) of the Act to waive certain payment or other program requirements may be necessary to carry out the provisions of the Shared Savings Program and to permit effective implementation of two-sided performance-based risk tracks under the program.

We noted in the proposed rule that while we were considering these waiver issues under the Shared Savings Program, we were also actively moving forward with testing certain payment rule and other waivers as part of models tested by the CMS Innovation Center under section 1115A of the Act, including the Pioneer ACO Model (see the CMS Web site at <http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/>). For example, we have early information and data from our initial test of the waiver of the SNF 3-day rule under the Pioneer ACO Model, and we are in the process of testing beneficiary attestation under the Pioneer ACO Model.

In addition, we would note that the CMS Innovation Center also recently announced the new Next Generation ACO Model (see the CMS Web site at <http://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/>). The goal of the Next Generation ACO Model is to test whether strong financial incentives for ACOs, coupled with tools to support better patient engagement and care management, can improve health outcomes and lower expenditures for Original Medicare fee-for-service (FFS) beneficiaries. Also central to the Next Generation ACO Model are several "benefit enhancement" tools to help ACOs improve engagement with beneficiaries, such as greater access to home visits, telehealth services, and skilled nursing facility services.

Finally, we also noted that it is possible that certain waivers of payment or program rules may only be appropriate under a model in which there is prospective assignment of beneficiaries, such as proposed Track 3. Under prospective assignment, beneficiaries would be assigned to the

ACO for the entire performance year, and it would thus be clear as to which beneficiaries the waiver applied. Having clarity as to whether a waiver applies to a particular beneficiary may be important for the ACO to comply with the conditions of the waiver and could also improve CMS' ability to monitor waivers for misuse.

As discussed in the sections that follow, we solicited comment on several options that would implicate the waiver authority under section 1899(f) of the Act and then considered other options that could be implemented independent of waiver authority. Although we did not specifically propose these options, we stated that we would consider the comments received regarding these options during the development of the final rule, and indicated that we might consider adopting one or more of these options in the final rule.

a. Payment Requirements and Other Program Requirements That May Need To Be Waived in Order To Carry Out the Shared Savings Program

In the proposed rule (79 FR 72816 through 72826), we discussed in detail a number of specific payment and program rules for which we believed waivers could be necessary under section 1899(f) of the Shared Savings Program statute to support ACOs' efforts to increase quality and decrease costs under two-sided performance-based risk arrangements, and on which we invited comments, as discussed later in this section. The payment and program rules are as follows:

(1) SNF 3-Day Rule

The Medicare SNF benefit is for beneficiaries who require a short-term intensive stay in a SNF, requiring skilled nursing, or skilled rehabilitation care, or both. Pursuant to section 1861(i) of the Act, beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days in order to be eligible for Medicare coverage of inpatient SNF care. MA plans may cover SNF care that is not preceded by a three day inpatient hospital stay; we believe this is appropriate because of the financial incentives for MA plans, which operate under a capitated payment arrangement, to control total cost of patient care. (See the discussion of this Medicare Advantage waiver of the three day qualifying inpatient hospital stay on the CMS Web site at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2016.pdf>, page 142.)

The Pioneer ACO Model has recently started testing whether a tailored waiver

of the SNF 3-day rule will enable the Pioneer ACOs to improve the quality of care for a subset of beneficiaries requiring skilled nursing, or skilled rehabilitation care, or both while also reducing expenditures. ACOs under the Pioneer ACO Model are accountable for the total costs of care furnished to their assigned beneficiary population, and must accept performance-based risk in the event that costs exceed their benchmark. This type of performance-based risk arrangement has the potential to mitigate the incentive to overuse SNF benefits.

(2) Billing and Payment for Telehealth Services

Under section 1834(m) of the Act, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. Generally, for Medicare payment to be made for telehealth services under the Physician Fee Schedule several conditions must be met. The services must be on the Medicare list of telehealth services and meet all of the following other requirements for payment:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the services must be in an eligible originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and provides separate payment to the distant site practitioner for the service. While certain professional services that are commonly furnished remotely using telecommunications technology are paid under the same conditions as in-person physicians' services, and thus do not require a waiver, ACOs and other commenters have suggested that a waiver of certain Medicare telemedicine payment requirements would help encourage a broader range of ACOs to more fully utilize telehealth, remote patient monitoring, and other such enabling technologies.

(3) Homebound Requirement Under the Home Health Benefit

In order for Medicare to pay for home health services, a beneficiary must be determined to be "home-bound." Specifically, sections 1835(a) and 1814(a) of the Act require that a physician certify (and recertify) that in the case of home health services under the Medicare home health benefit, such

services are or were required because the individual is or was "confined to the home" and needs or needed skilled nursing care on an intermittent basis, or physical or speech therapy or has or had a continuing need for occupational therapy. A beneficiary is considered to be confined to the home if the beneficiary has a condition, due to an illness or injury, that restricts his or her ability to leave home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the beneficiary has a condition such that leaving his or her home is medically contraindicated. While a beneficiary does not have to be bedridden to be considered confined to the home, the condition of the beneficiary must be such that there exists a normal inability to leave home and leaving home requires a considerable and taxing effort by the beneficiary. Absent this condition, it would be expected that the beneficiary could typically get the same services in an outpatient or other setting. Thus, the homebound requirement provides a way to help differentiate between patients that require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting.

Some ACOs and others have suggested that a waiver of this requirement would be appropriate under the Shared Savings Program, especially for ACOs that have elected to participate under a two-sided performance-based risk arrangement. They suggested that home health care would be appropriate for additional beneficiaries and could result in lower overall costs of care in some instances. For example, some had suggested, based on their experiences outside of the Medicare FFS program, that if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered home-bound, the beneficiary may avoid a hospital admission.

(4) Waivers for Referrals to Post-Acute Care Settings

As a condition of participation (CoP) in Medicare, a hospital must have in effect a discharge planning process that applies to all patients, as required under § 482.43. The Interpretative Guidelines for this requirement found in the State Operations Manual, Publication 100-07, Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, section A-0799, define hospital discharge planning as a process that involves determining the appropriate post-hospital discharge

destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his or her discharge destination; and beginning the process of meeting the patient's identified post-discharge needs. The discharge planning CoP requires the hospital to develop a discharge planning evaluation at the patient's request and to discuss the evaluation and plan with the patient and actively involve patients or their representatives throughout the discharge planning process. When applicable, the hospital must include in the discharge plan a list of home health agencies (HHAs) or SNFs that are available to the patient, that are participating in the Medicare program and that serve the geographic area (as defined by the HHA) in which the patient resides or, in the case of a SNF, in the geographic area requested by the patient. During the discharge planning process the hospital must inform the patient or the patient's family of their freedom to choose among Medicare-participating post-hospital providers and must not direct the patient to specific provider(s) or otherwise limit which qualified providers the patient may choose among. When the patient or the patient's family has expressed a preference, the hospital must attempt to arrange post-hospital care with an HHA or SNF, as applicable, consistent with that preference. If the hospital is unable to make the preferred arrangement (for example, if there is no bed available in the preferred SNF), it must document the reason the patient's preference could not be fulfilled and explain that reason to the patient.

ACOs and MedPAC have indicated that as ACOs have started to analyze claims data on their beneficiaries, they are recognizing that certain providers may deliver higher-quality and lower-cost care than others. ACOs have indicated that they would like to have the ability to recommend high-quality SNF and HHA providers with whom they have established relationships, rather than presenting all options equally. ACOs have asked that we provide clear direction on how preferred providers can be presented to beneficiaries and what represents clear notification of the beneficiary's freedom to choose among participating Medicare providers.

(5) Solicitation of Comments on Specific Waiver Options

In the December 2014 proposed rule, although we did not propose changes to our program rules that would implicate waivers of payment and other program rules, we sought comments on the

following specific waivers of payment and other program rules that would implicate the waiver authority under section 1899(f) of the Act:

- **SNF 3-Day Rule.** We sought comment (79 FR 72817 through 72820) on whether a waiver of the 3-day SNF rule was necessary for purposes of implementing two-sided performance based risk models under the Shared Savings Program. We indicated that if we were to make such a waiver available in the Shared Savings Program then initially it would likely be made available only to ACOs in Track 3 for their prospective assigned beneficiary population. We indicated that we would likely offer ACOs the opportunity to apply for such a waiver using a framework similar to the one currently developed under the Pioneer ACO Model, with appropriate revisions as necessary to accommodate the differences in beneficiary assignment methodology. However, we sought comment on whether such a waiver should apply to all performance-based risk tracks and considered options for identifying eligible beneficiaries under a retrospective assignment methodology. We indicated that under any such waiver ACOs would be required to submit to CMS for approval of a SNF or group of SNFs with which they wish to partner. In addition, we stated that we believed it would be appropriate to limit such a waiver to SNFs that are ACO participants or ACO providers/suppliers because these entities would have incentives that are most directly aligned with those of the ACO.

- **Billing and Payment for Telehealth Services.** We sought comment (79 FR 72820 through 72822) on an option that would waive the originating site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000. We also sought comment on an option that would provide a waiver of the originating site requirements of section 1834(m)(4)(C)(ii)(I) through (VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. We indicated that any such a waiver would likely be limited for use by Track 3 ACOs for their prospectively assigned beneficiaries. We sought comments on whether it is necessary to use the waiver authority under section 1899(f) to allow ACOs additional flexibility to provide a more extensive

set of telehealth services or services in a broader range of geographic areas and a number of factors related to the scope of any such waiver.

- **Homebound Requirement Under the Home Health Benefit.** We sought comment (79 FR 72822 through 72823) on whether a waiver of the homebound requirement under section 1899(f) of the Act is necessary in order to carry out the Shared Savings Program. Specifically, we sought comment on an option that would offer an ACO participating under Track 3 the opportunity to provide home health services to non-home bound beneficiaries that are prospectively assigned to the ACO, and requested additional comment on related implementation issues. We indicated that to help ensure that the waiver is used appropriately, we would require that home health services provided pursuant to the waiver be at the direction of an ACO provider/supplier that is not a home health agency. We also noted that the home health agency would likely be required to be an ACO provider/supplier. However, in any case, the ACO would be required to submit to CMS the home health agency or group of home health agencies with which it wishes to partner in providing services pursuant to this waiver.

- **Referrals to Post-acute Care Settings.** We sought comment (79 FR 72823 through 72826) on whether it is necessary to waive the requirement under section 1861(ee)(2)(H) of the Act that a hospital "not specify or otherwise limit the qualified provider which may provide post-hospital home services" and the portions of the hospital discharge planning CoP at 42 CFR 482.43 that implement this requirement, using our waiver authority under section 1899(f) of the Act for ACOs participating in two-sided risk tracks under the Shared Savings Program. We indicated that if we were to implement such a waiver, we would likely limit the use of the waiver to beneficiaries prospectively assigned to ACOs participating under Track 3. We also noted that we believed it would be appropriate to limit such a waiver to hospitals that are ACO participants or ACO providers/suppliers because these entities would have incentives that are most directly aligned with those of the ACO. We stated that under a waiver of the prohibition on the specification of qualified providers, discharge planners in hospitals that are ACO participants or ACO providers/suppliers would have the flexibility to recommend high quality post-acute providers with whom they have relationships (either financial, or clinical, or both) for the purpose of

improving continuity of care across sites of care.

- **Waiver of Other Payment Rules.** In the proposed rule (79 FR 72826), we also welcomed suggestions on whether there are any additional Medicare FFS payment rules that it may be necessary to waive using our authority under section 1899(f) of the Act in order to effectively implement two-sided risk financial arrangements under the Shared Savings Program by providing additional mechanisms for ACOs to increase quality and decrease costs. We indicated that we would establish any such waivers through the rulemaking process.

Comments: A majority of commenters supported all four waivers. Most commenters supported applying these waivers very broadly to all tracks and all FFS patients receiving services from ACO participants and ACO providers/suppliers, stating that waiver of payment requirements and other regulations is necessary for ACOs in all tracks to optimally coordinate care and reduce costs. These commenters generally believe that ACOs participating in each track can produce savings for CMS and improve value and quality for Medicare beneficiaries. Therefore, they recommended that ACOs participating under all 3 tracks should have an opportunity to apply for these four potential payment and program requirement waivers. Under this approach, the determination of whether an organization can appropriately use these waivers would be based on the strength of an ACO's waiver application and past performance, not its risk track. Some commenters believe that these waivers should be available not only to assigned beneficiaries but rather to all beneficiaries who have had at least one primary care service from an ACO provider/supplier. Some commenters suggested that for quality control, CMS could use a screening mechanism (for example, the application process) and ongoing monitoring of all ACOs participating in waivers to ensure participating ACOs are able to fulfill the requirements for the waivers.

A few commenters disagreed that the waivers offered any additional incentive to move to two-sided risk because ACOs have demonstrated they can improve quality and reduce costs without them. A few commenters expressed concerns that incorporating such waivers in FFS Medicare without providing the same flexibilities for MA plans could create inappropriate incentives for MA plans to leave and become ACOs or for providers that contract with MA plans to leave such plans and instead join or

form ACOs. MedPAC and several others agreed that regulatory relief should be incorporated into the Shared Savings Program, but that the waivers should be limited to Track 3 or only applied when there is prospective assignment of beneficiaries or both so that CMS may process claims appropriately and provide oversight of their use. Other commenters also expressed concern with applying the waivers beyond Track 3, stating they believed that doing so would create a disincentive for ACOs to accept additional risk. Some commenters supported the waivers but cautioned that additional protections should be incorporated to guard against stinting of care. At least a commenter suggested limiting waiver use to ACOs that choose two-sided risk after having successfully completed at least one agreement period under Track 1.

More specific comments related to each waiver option for which we sought comment are as follows:

- **SNF 3-Day Waiver:** A majority of commenters supported a waiver of the SNF 3-day rule. In contrast, several commenters strongly opposed use of a SNF 3-day waiver for any ACO, regardless of track or criteria. Some stated that they believe Shared Savings Program ACOs have the potential to endanger patients' health outcomes and that ACOs lack adequate oversight and the waiver options include insufficient protections for beneficiaries. Some stated that they viewed the discussion of a potential waiver of the SNF 3-day rule as driven by a governmental attempt to save money at the expense of beneficiary choice and quality of care. Some expressed concern that such a waiver would inappropriately incentivize migration of care to SNFs over other post-acute options, or that costs would be shifted to the Medicaid program because patients could be referred to SNFs preferentially over IRFs and become long-stay residents. Some recommended a cautious and incremental approach to the application of such a waiver, and recommended that CMS gather evidence from testing prior to incorporating it in the Shared Savings Program.

Some commented on criteria for use of the waiver, such as requiring an ACO physician's signature for admission to a SNF and aligning the waiver criteria with those established for the Pioneer ACO Model, under which the patient must be medically stable, not require an inpatient evaluation or treatment and have a skilled nursing or rehabilitation need that could not be provided as an outpatient. Some commenters suggested that we should allow a waiver of the 3-day SNF rule only for patients with

certain highly prevalent, high-cost chronic conditions. At least one commenter believes the criteria used under the Pioneer ACO Model are not strong enough independently, or together, to ensure high quality of care for SNF patients assigned to ACOs using the waiver. Commenters suggested that we should closely monitor waiver use and rescind the waivers "for cause." Most commenters generally agreed that waivers should only be granted to SNFs that are ACO participants or ACO providers/suppliers, although a few opposed this limitation, stating that limiting the waiver to some subset of SNFs could limit patient access, particularly in rural areas, and override patient preference or choice.

In addition, several made comments about SNF quality of care. For example, some commenters supported requiring SNFs to have a quality rating of 3 or more stars under the CMS 5 Star Quality Rating System, as reported on the Nursing Home Compare Web site in order to participate in the use of a waiver. Some commenters suggested that the quality criteria should apply more broadly; that is, SNFs should be required to earn a 3-star rating in order to be an ACO provider/supplier.

However, other commenters believe that earning a 3-star rating is insufficient evidence of a SNF's readiness to treat patients that are admitted pursuant to a waiver and cited a recent New York Times article and OIG report. At least one commenter suggested that SNFs be required to have at least a 4-star rating in order to be eligible to receive patients pursuant to a waiver. Some commenters recommended that a 3-star rating should be required not only for the SNF's overall rating but should also apply to each composite rating.

- **Telehealth Waiver:** Most commenters supported a telehealth waiver that would remove geographic and originating site requirements for ACOs participating in all tracks or all two-sided risk tracks. Some commenters believe we should consider allowing all ACOs (including Pioneer ACOs) to apply for a waiver to bill for telehealth services for any patient. In particular, high-risk, frail patients may benefit from such a waiver if they are unable to get to a physician office in a timely manner. Some patients, who may be reluctant to make an appointment for a simple problem because of scheduling conflicts, leave their medical condition unchecked, often leading to more serious health issues. For these patients, the commenters believe the convenience of telehealth may encourage them to seek advice from their medical care team for non-emergent medical

conditions, potentially avoiding unnecessary use of the emergency room. The commenters believe use of telehealth has been demonstrated to be beneficial for patients who have certain chronic diseases (COPD and CHF) where minor daily changes in their health status can trigger an exacerbation and subsequent hospitalization. Commenters varied considerably as to the services that they believe should be included within the definition and scope of a telehealth waiver. For example, some commenters were supportive of waiving requirements regarding originating site, or geographic areas, or both for currently billable services whereas other commenters suggested waivers that would cover a broader range of additional services such as including the use of bi-directional audio/video, physiologic and behavioral monitoring, "engagement prompts," remote monitoring, store and forward technologies, and point-of-care testing.

Some commenters suggested a phase-in or pilot testing of a telehealth waiver to assist with implementation and application to all tracks. Some commenters suggested a phase-in of additional telehealth flexibility, including remote patient monitoring, for ACOs based on their level of financial risk and "beneficiary management." Some commenters suggested that CMS should use its waiver authority to allow ACOs to define the specific technologies, conditions, and services that they would use in the provision of care and CMS would then evaluate which services improved care delivery efficiency and quality. This phased approach would also allow newer ACOs to learn from the experience of the more advanced ACOs that are bearing greater financial risk. To limit new spending under the waiver, some commenters suggested that CMS could control the scope of the waiver by applying it only to telehealth services for a limited set of conditions; these conditions could encompass chronic conditions, such as diabetes, chronic obstructive pulmonary disease, and congestive heart failure, as well as more acute post-operative conditions including overall health, pain, fever, incision appearance, activity level, and any patient post-operative concerns. The commenters believe limiting the scope of the waiver would allow CMS to test the effects of the use of telehealth services and remote patient monitoring in these critical populations, while ensuring that the policy is well-defined. Some commenters also believe that those who provide telemedicine services must abide by certain standards

of care, and that these standards must be part of the waiver requirements. Some commenters oppose any monitoring or requirements that would increase the reporting burden of the ACO.

Some commenters noted that there are times when telehealth may not be appropriate—for example, when there is a cognitive impairment, when diagnostic testing is needed, when the condition is severe, when a hands-on examination is needed, or if there is an uncertain diagnosis. A few commenters expressed concern about whether the expansion of the use of telehealth services within the Shared Savings Program may lead to inappropriate utilization through the 340B drug discount program in the absence of more detailed guidance on the interaction of the two initiatives. These commenters requested that CMS work with the Health Resources and Services Administration (HRSA), which administers the 340B program, to affirm that it is not our intention for the receipt of telehealth services within the context of the Shared Savings Program to, in and of itself, qualify a beneficiary as a patient of 340B covered entity. These commenters are concerned that without such a clarification and necessary oversight in place, patients may be unduly encouraged to seek telehealth services even when in-person services are available and more appropriate.

• **Homebound Requirement Waiver:** Most commenters supported a waiver of the homebound requirement for all tracks. Some of these commenters acknowledge there is a possibility that home health utilization increases could exceed the corresponding savings from lower inpatient utilization. However, the commenters believe the potential improvements in care and outcomes across all participants as a result of this waiver far outweigh the remote risks to the Medicare Trust Fund. Some strongly recommended a phase-in approach or prior pilot testing before offering such a waiver to all tracks. For example, some commenters recommended that CMS should test and measure the impact of this waiver with qualified Track 1 ACOs and that CMS should implement this waiver immediately for Track 2 and Track 3 ACOs, because Track 2 and Track 3 ACOs are already adequately incentivized to manage cost and quality. A few commenters were strongly in opposition to implementing a waiver of the homebound requirement, stating that the homebound requirement is necessary to avoid abuse and overuse of home health services. Some commenters agreed that there is benefit to the home health agency being an ACO participant or ACO provider/supplier and that the

home health agency should be required to have a 3-star quality rating (or better), whereas other commenters opposed these requirements. Some commenters, for example, believe that ACOs should have the flexibility to determine which partners, participants, and vendors it believes best fit within its integration of care as it is at financial risk in such decisions. Some commenters believe the Home Health star rating system requires further refinement and that the Home Health star ratings require appropriate risk-adjustment.

• **Post-Acute Referral Waiver:** Support for the waiver for post-acute referrals was more mixed than for the other waivers. For those that supported this waiver, most would support a waiver for all tracks. These commenters believe a waiver would allow participants to provide informed recommendations to patients without limiting choice and without increasing utilization. They further suggest that ACOs in all tracks already have adequate incentives to ensure patients receive care from the highest quality, most efficient providers in the market. Some of the commenters that supported such a waiver believe that the waiver should be limited to hospitals that are ACO participants or ACO providers/suppliers, that any recommended post-acute care provider meet certain quality criteria, and that the ACO provide a brief written description in its waiver application describing how it would use the waiver to meet the clinical needs of its assigned patients.

Some expressed support for such a waiver only if additional conditions apply, such as including a requirement that patients should be notified in advance that providers and suppliers participating in an ACO may direct patients to certain pre-identified post-acute care providers. These commenters believe that CMS must closely monitor the use of the waiver to ensure beneficiaries maintain full freedom of choice.

Some commenters were strongly opposed to or expressed strong concerns about waiving the post-acute care requirements. Some strongly oppose allowing hospitals to refer patients solely to providers with which they have financial relationships. These commenters believe that such a waiver would infringe on the right of beneficiaries to choose the best provider for their needs or undermine patient selection of high quality post-acute care providers. Some expressed concern that patients would be inappropriately steered toward SNFs in lieu of IRFs, even when IRFs are available in the geographic area and are the most

medically appropriate post-acute setting for the patient, solely because their charges to the Medicare program are higher than SNF charges. Some commenters requested a clarification that the waiver applies to ACOs and not just hospitals, since some ACOs do not include any hospitals as participants.

- Other Payment Rule Waiver

Suggestions: Commenters suggested many other payment rules that they believed we should consider for a waiver, such as the following:

- ++ Waiving the two-midnight inpatient admission criteria.
- ++ Relief from RAC audits.
- ++ Waiving the face-to-face home health requirement.
- ++ Waiving hospice rules to permit ACOs to enroll individuals in hospice even if they are receiving curative treatment.
- ++ Waivers that would permit non-physician practitioners to certify patients for home health services.
- ++ Waiving the intermittent care requirement so that patients requiring intermittent care would not be “forced to receive care from a skilled nursing facility” but instead could receive home health care, if appropriate.
- ++ Waiving rules to permit home health agencies to perform pre- and post-operative assessments.
- ++ Waiving certain Shared Savings Program rules such as the requirement that a physician visit is a prerequisite for assignment.
- ++ Waiving FFS payment rules to compensate ACO providers for currently unfunded activities such as care manager services, paramedic evaluations, or services provided by community health workers.

Response: We appreciate the many thoughtful suggestions, which will be helpful to us in developing any future proposals regarding the waiver of any Medicare FFS rules that might be necessary to carry out the Shared Savings Program, and in particular to implement two-sided risk models under the program. We agree with commenters who believe that waivers of certain FFS payment rules and other requirements could be a beneficial addition to the Shared Savings Program.

However, in order to waive a statutory requirement using the waiver authority under section 1899(f) of the Act, the waiver must be necessary in order to carry out the provisions of section 1899 of the Act. With the exception of the waiver of the SNF 3-day rule, we need additional time to assess whether any of the waivers discussed in the proposed rule or suggested by commenters are necessary for the operation of the Shared Savings Program. We intend to

consider this issue further and will carefully examine lessons learned regarding the waivers that are being tested as part of Innovation Center models and in the event that we determine that additional waivers are necessary to carry out the Shared Savings Program, we will propose them in future rulemaking.

As noted previously, we are encouraged by the robust participation of organizations under the one-sided model of the Shared Savings Program. However, we continue to believe that the long term effectiveness and sustainability of the program depend on encouraging ACOs to progress along the performance-based risk continuum. Given the limited ACO interest thus far in two-sided performance-based risk, and the comments and suggestions by stakeholders, we believe that use of the authority under section 1899(f) of the Act to waive certain payment or other program requirements is necessary to carry out the provisions of the Shared Savings Program and to permit effective implementation of two-sided performance-based risk tracks under the program. As discussed previously in the April 2011 and December 2014 proposed rules, both we and many commenters believe that models where ACOs bear a degree of financial risk hold the potential to induce more meaningful systematic change than one-sided models. We believe that ACOs that bear financial risk would have a heightened incentive to restrain wasteful spending by their ACO participants and ACO providers/suppliers. This, in turn, may reduce the likelihood of over-utilization. In these circumstances, we believe that it is necessary to use our authority under section 1899(f) to waive the SNF 3-day rule under section 1861(i) of the Act in order to carry out the provisions of section 1899 of the Act by offering ACOs that have accepted two-sided risk under the Shared Savings Program more flexibility under FFS Medicare to provide appropriate care for beneficiaries in the most appropriate care setting.

Because we believe a waiver of the SNF 3-day rule under section 1899(f) of the Act is necessary in order to carry out the Shared Savings Program, and because we have already developed key program details through the Pioneer ACO Model that can be readily adopted under the Shared Savings Program, in this final rule we are providing for a waiver under part 425 of the SNF 3-day rule for certain SNF services furnished to eligible beneficiaries that are prospectively assigned to ACOs that participate in Track 3. An ACO's use of

the 3-day SNF rule waiver will be associated with a distinct and easily identified event (admission of a prospectively assigned beneficiary to a SNF without prior hospitalization or after an inpatient hospitalization of fewer than 3 days). This waiver under part 425 will be effective for services furnished on or after January 1, 2017. This timeline will allow for development of additional subregulatory guidance, including necessary education and outreach for ACOs, ACO participants, ACO providers/suppliers and SNFs. At this time we are limiting the waiver to ACOs in Track 3 because under the prospective assignment methodology used in Track 3, beneficiaries will be assigned to the ACO for the entire performance year, and it will be clearer to the ACO as to which beneficiaries the waiver applies than it would be to an ACO in Track 1 or 2 under preliminary prospective assignment. We believe that having clarity as to whether the waiver would apply to SNF services furnished to a particular beneficiary is important to allow the ACO to comply with the conditions of the waiver and could also improve our ability to monitor waivers for misuse.

We are including the program requirements for this waiver of the SNF 3-day rule under the Shared Savings Program in a new provision that we are adding at § 425.612 of the regulations. We are not only adopting specific program requirements for the SNF 3-day rule waiver, but also more general requirements that will apply to all payment and program rule waivers under the Shared Savings Program. These requirements are primarily based on the program criteria previously developed under the Pioneer ACO Model. Specifically, we are waiving the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare covered post-hospital extended care service for eligible beneficiaries prospectively assigned to ACOs participating in Track 3 that receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply. We would emphasize that under this waiver CMS is not expanding Medicare SNF coverage to patients who could be treated in outpatient settings or who require long term custodial care. Through this waiver CMS is not creating a new benefit, but

instead we are providing ACOs participating in Track 3 with additional flexibility to increase quality and decrease costs. The SNF benefit itself will remain otherwise unchanged.

All ACOs electing to participate in Track 3 will be offered the opportunity to apply for a waiver of the SNF 3-day rule for their prospectively assigned beneficiaries at the time of their initial application to the program. In their request to use the waiver, ACOs must demonstrate that they have the capacity to identify and manage patients who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days. Specific criteria will be set forth in the materials for both initial applications and renewals under Track 3. CMS will provide further information regarding the application, process, including the application and specific requirements such as the deadline for submitting waiver requests, through subregulatory guidance and will also provide a feedback process to afford an opportunity for the applicant to clarify or revise its waiver request to meet the requirements. This waiver of the SNF 3-day rule under the Shared Savings Program under part 425 will be implemented consistently across all eligible ACOs. In other words, the waiver will be uniformly applied, and there will not be customization of the waiver or specific conditions for the waiver for particular eligible ACOs. CMS does not intend for ACOs to select SNFs on the basis of willingness to pay (or actual payment) for participation (for example “pay to play”). We intend to monitor this issue and, if necessary, will modify the waiver to address any abuses in selection of SNFs in future rulemaking. At this time we are not requiring eligible ACOs to obtain a surety bond or other financial instrument to cover the costs of inappropriate SNF admissions, but we may consider adding such a requirement in future rulemaking.

The materials that must be submitted as part of the waiver request include but are not limited to the following:

- Narratives describing how the ACO plans to implement the waiver. For example, all eligible ACOs interested in applying for the SNF 3-day waiver will be required to provide an overview of how the care for patients admitted to a SNF pursuant to this waiver will be clinically integrated across sites and describe the system of care that will be implemented—including how the ACO will assess whether care is improving while decreasing cost growth. In addition all eligible ACOs interested in applying for the waiver will be required

to describe how beneficiaries will be assessed, with input from the ACO medical director, to determine whether a SNF is the best site for admission (vs. acute care hospital or other post-acute care facility), including how they will determine that the beneficiary does not require the intensity of an acute care hospital admission, but does require the level of skilled nursing and rehabilitation care or both provided in a high performing SNF. More specifically, as part of the narratives describing how the ACO plans to implement the waiver, eligible ACOs will also be required to describe their: (1) Communication plan between ACO participants and the SNFs participating in the waiver; (2) care management plan for beneficiaries that are admitted to a SNF pursuant to this waiver; (3) beneficiary evaluation and admission plan, which must be approved by the ACO medical director and the healthcare professional responsible for the ACO’s quality improvement and assurance program, that includes: The protocol that will be followed for evaluating and approving admissions to a SNF pursuant to the waiver and consistent with the beneficiary eligibility requirements described in the next paragraph; that provides for the ACO medical director or qualified healthcare professional to be available to respond to inquiries related to application of the waiver; and provides for education and training for eligible SNFs regarding waiver requirements, and (4) the financial relationship between the ACO, participating SNFs, and acute care hospitals. These requirements would be similar to the narratives that are already required as part of the application to participate in the Shared Savings Program to explain how ACOs will implement the required care processes under § 425.112. ACOs must then periodically evaluate and update these processes.

- A list of SNFs with whom the ACO will partner along with executed written agreements.

- Documentation demonstrating that the SNF has an overall quality rating of 3 or more stars under the CMS 5 Star Quality Rating System, as reported on the Nursing Home Compare Web site.

In order to be eligible to receive covered SNF services under the waiver, a beneficiary must meet the following requirements:

- Is prospectively assigned to the ACO for the performance year in which they have a SNF admission.
- Does not reside in a SNF or other long-term care setting.
- Is medically stable.

- Does not require inpatient or further inpatient hospital evaluation or treatment.

- Have certain and confirmed diagnoses.

- Have an identified skilled nursing or rehabilitation need that cannot be provided as an outpatient.

- Have been evaluated and approved for admission to the SNF within 3 days prior to the SNF admission by an ACO provider/supplier who is a physician, consistent with the beneficiary evaluation and admission plan.

To provide flexibility for ACOs, we are not requiring that SNFs be an ACO participant or ACO provider/supplier in order to be eligible to partner with an ACO for purposes of the waiver, although they must be Medicare-enrolled entities in good standing. We agree with some commenters who believe that limiting the waiver to SNFs that are ACO participants or ACO providers/suppliers could limit patient access, particularly in rural areas, and override patient preference or choice. Furthermore, under the Pioneer ACO Model, eligible SNFs are not required to be participating in the Pioneer ACO. However, we agree with commenters who believe that there should be strong evidence of collaboration between the ACO and SNF related to the objectives of the Shared Savings Program. Therefore, the following requirements apply in order for a SNF to be eligible to partner with ACOs for purposes of the waiver:

- Similar to the current requirement under the Pioneer ACO Model, for purposes of this waiver under part 425, an eligible SNF must have an overall quality rating of 3 or more stars under the CMS 5 Star Quality Rating System, as reported on the Nursing Home Compare Web site at the time of selection and must maintain that rating in order to continue to partner with an ACO for purposes of this waiver. We believe incorporating this requirement under the Shared Savings Program will provide beneficiaries with evidence that the SNF provides quality care.

- An eligible SNF must sign a written agreement with the ACO, which we will refer to as the “SNF Affiliate Agreement” that includes elements determined by CMS, including: A clear indication of the effective dates of the SNF affiliate agreement; agreement to comply with Shared Savings Program rules, including but not limited to those specified in the participation agreement; agreement to comply with and training on both the ACO’s beneficiary evaluation and admission plan and the care management plan for beneficiaries that are admitted to a SNF pursuant to

this waiver; agreement to validate beneficiary eligibility for the waiver prior to admission; and remedial processes and penalties for inappropriate use of the waiver. The SNF Affiliate Agreement must include these elements in order to ensure that the SNF is able to determine prior to admission whether a beneficiary is prospectively assigned to the Track 3 ACO with which the SNF has an agreement and whether the admission has been ordered by an ACO provider/supplier who is a physician so that the SNF will know when it can appropriately bill for services furnished to an eligible beneficiary who does not have a 3-day inpatient stay.

- Eligible SNFs will be screened during the waiver application review process and periodically thereafter, with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.

The waiver will be effective no earlier than January 1, 2017; thereafter, the waiver will be effective upon CMS notification of approval for the waiver or the start date of the participation agreement, whichever is later, and will not extend beyond the term of the ACO's participation agreement. If CMS terminates the participation agreement under § 425.218, then the waiver will end on the date of the notice of termination or on a later date to be determined by CMS in order avoid disrupting patient care or transitions. We believe that this additional flexibility to determine the end date is appropriate to provide us with an opportunity to address potential concerns about beneficiary liability for SNF services received after the date of the notice of termination. If the ACO terminates its participation agreement, then the waiver will end on the effective date of termination as specified in the written notification required under § 425.220.

ACOs with approved waivers will be required to post their use of the waivers, and will also be required to post a list of SNFs with which the ACO has a signed written SNF Affiliate Agreement for purposes of the waiver, as part of public reporting on their dedicated ACO Web page. We are revising § 425.308 to add this requirement at paragraph (b)(6).

Further, we will monitor and audit the use of such waivers under § 425.316. We anticipate implementing heightened monitoring of entities that bill under this payment rule waiver to help reduce the possibility for abuse of the waiver. We also intend to give heightened

scrutiny to any marketing materials or activities by ACOs or by eligible SNFs that relate to services for which there may be an applicable waiver of the SNF 3-day rule to prevent coercive or misleading marketing. Additionally, we will require the ACO to continually monitor and evaluate its processes for assessing beneficiaries for admission to a SNF pursuant to the waiver, similar to the requirement under § 425.112 that ACOs evaluate and periodically update their required processes and patient-centeredness criteria.

We reserve the right to deny or revoke an ACO's participation in this waiver if the ACO, the ACO participants, the ACO providers/suppliers, or other individuals or entities (including SNFs) providing services to Medicare beneficiaries pursuant to this waiver are not in compliance with requirements under the Shared Savings Program, if the ACO does not use the waiver as described in its application, or if the ACO does not successfully meet the quality performance standard. We believe that the ACO's failure to meet the quality performance standard raises questions as to whether the ACO has the capacity to properly monitor the use of the waiver and to evaluate when beneficiaries are eligible for admission to a SNF under the terms of the waiver. We note that under § 425.304(b) we perform routine screening at the time of application and at other times during the ACO's agreement period. We reserve the right to deny participation in or revoke participation in this waiver if program integrity issues are uncovered as a result of the screening.

The waiver will not protect financial or other arrangements between or among ACOs, ACO participants, ACOs providers/suppliers, or other individuals or entities providing services to ACO patients from liability under the fraud and abuse laws or any other applicable laws. Additionally, this waiver only protects the submission of claims that meet all applicable requirements except the requirement for a prior 3-day inpatient stay. In other words, waivers are only granted for the regulatory exceptions expressly permitted under the waiver. No other applicable payment regulations are waived. Therefore, ACOs, ACO participants, ACO providers/suppliers and SNFs must comply with all applicable claims submission requirements.

We would also note that we will continue to evaluate the waiver of the SNF 3-day rule, including further lessons learned from Innovation Center models in which a waiver of the SNF 3-day rule is being tested. In the event that

we determine that additional safeguards or protections for beneficiaries or other changes are necessary, such as to incorporate additional protections for beneficiaries into the participation agreement or SNF Affiliate Agreements, we will propose the necessary changes through future rulemaking.

However, regarding the other waivers of payment and program rules under part 425 discussed in the proposed rule, based on a review of the comments and experience gained thus far with ACO models, we continue to have concerns that immediately adopting untested or unproven waivers with which we have little experience on a national scale could lead to unintended consequences for the FFS beneficiaries we serve or for the health care system more broadly. There are many important details that must be designed and implemented to appropriately maintain beneficiary, provider and program protections under a waiver. Therefore, at this time we are not adopting any additional waivers under part 425 other than a waiver of the SNF 3-day rule. Instead, we expect to take a phased approach to the introduction of additional waivers with testing by the CMS Innovation Center prior to any decision as to whether it is appropriate to implement a particular waiver in the Shared Savings Program. More specifically, we expect to initially focus on further development of a waiver under part 425 of certain billing and payment requirements for telehealth services. We intend to offer such a waiver starting as early as in 2017, with specific requirements to be determined based on CMS' experience implementing such a waiver in the Next Generation ACO Model. We believe that providing ACOs that participate in the Shared Savings Program under two-sided performance based risk arrangements with additional flexibility to expand appropriate use of telehealth services has significant potential to improve patient care, improve communication between patients and their families and health care providers, support more timely treatment, and help to address barriers to access to care for some beneficiaries, such as those that require treatment or consultations with certain specialists. We believe that it may be necessary to use our authority under section 1899(f) of the Act to waive certain payment or other program requirements for telehealth services, for the same reasons that we have determined that a waiver of the SNF 3-Day Rule is necessary to carry out the Shared Savings Program in order to permit effective implementation of two-sided performance-based risk tracks

under the program. We believe that a waiver of certain telehealth-related rules under part 425 for ACOs participating under a two-sided risk model may be necessary in order to give ACO participants and ACO providers/suppliers more flexibility under FFS Medicare to provide appropriate and timely care for assigned beneficiaries. At this time, we anticipate that we would initially limit any waiver to ACOs in Track 3 because under the prospective assignment methodology used in Track 3, beneficiaries will be assigned to the ACO for the entire performance year, and it will be clearer to the ACO as to which beneficiaries the waiver applies than it would be to an ACO in Track 1 or 2 where beneficiaries are assigned using a preliminary prospective assignment methodology.

In regards to the concerns raised by some commenters regarding a possible interaction between a telehealth waiver and the 340B Drug Pricing Program, we note that we are aware that HRSA, which administers the 340B Drug Pricing Program, is currently considering issuing guidance on key areas in the 340B Program. If, in the future, we develop a proposal for a waiver of any telehealth payment rules within the Shared Savings Program, we intend to work closely with HRSA to address concerns about interactions between such a waiver under part 425 and HRSA programs, including the 340B Program.

We plan to test a waiver of certain telehealth payment rules as part of the Next Generation ACO Model being tested through the CMS Innovation Center. The benefit of this approach is that it will provide flexibility to permit testing of such a waiver prior to implementation of any waiver on a larger scale in the Shared Savings Program. Through such testing we frequently identify issues that neither we nor stakeholders had previously identified. Developing and implementing waivers in a test environment provides an opportunity for us to better understand the effects on providers, beneficiaries, and Medicare. Additionally, testing provides an opportunity to fine tune operations and to make any necessary modifications quickly to refine the waiver to address concerns, such as if the waiver implementation is determined to be too burdensome to ACOs or harmful to beneficiaries.

Comment: Commenters provided suggestions for waivers of certain fraud and abuse rules, or other rules including the following:

- A waiver that would allow ACOs to provide beneficiaries with incentives to

receive services within the ACO, such as a waiver of some or all beneficiary “co-pays” or allowing ACOs to allocate a certain percentage of their shared savings directly to patients.

- A waiver that would allow ACOs to cover additional costs that they deem as being necessary for chronic care management, such as additional telehealth-related services, transportation, wheelchairs and other medical equipment, gym or wellness program memberships, heating or air conditioning, home improvements, including railing installation or other modifications to ease movement.

Response: Any waiver of fraud and abuse rules would be addressed by OIG and CMS separately from payment and program rule waivers. We recognize that in certain circumstances where there is no Medicare coverage for a particular item or service, some ACOs want to be able to offer additional beneficiary incentives that they deem as being necessary for chronic care management such as additional telehealth or other services suggested by commenters. We addressed these issues in our November 2011 final rule (see § 425.304(a)). Subject to compliance with all other applicable laws and regulations, an ACO, its ACO participants, its ACO providers/suppliers, or entities performing functions or services related to ACO activities may provide beneficiaries items or services for free or below fair market value if both of the following conditions are met:

- There is a reasonable connection between the items or services and the medical care of the beneficiary.
- The items or services are in-kind and either are preventive care items or services or advance one or more of the following clinical goals: Adherence to a treatment regime; adherence to a drug regime; adherence to a follow-up care plan; or management of a chronic disease or condition.

Also, the authority at section 1899(f) of the Act has been used by the Office of Inspector General and CMS to issue an interim final rule with comment period setting forth waivers of certain fraud and abuse authorities (“Waiver IFC”), which was published concurrently with the November 2011 final rule establishing the Shared Savings Program (76 FR 67992). On October 17, 2014, HHS published a continuation notice (79 FR 62356) to extend the effectiveness of the Waiver IFC for 1 year (that is, until November 2, 2015). The Waiver IFC, as may be modified or updated from time to time, addresses certain issues related to the provision of in-kind beneficiary incentives under § 425.304.

Comment: Some commenters stated that any waivers and related standards should be applied consistently across entities—in this case, all Shared Savings Program ACOs as well as MA plans that bear risk for the cost and quality of care. Regarding non-traditional benefits being offered to a subset of the ACO’s population, a few commenters noted that there are situations where MA plans have wanted to offer benefits to members that would have improved their care experience, but have been unable to do so as a result of the supplemental benefits rules outlined in Chapter 4 of the Medicare Managed Care Manual. For example, one MA plan offers supplemental benefits such as transportation and home food delivery as part of care management programs but is bound by the supplemental benefits rules, which require uniformity, anti-discrimination and access (Chapter 4, Section 10.5 of the Medicare Managed Care Manual and 42 CFR 422.100(e)(2)). The commenter stated that it would be helpful if MA plans (and ACOs) could offer such supplemental benefits as part of a robust care management program, even if the program is targeted to the subset of the plan’s population most likely to benefit from the services. In situations like this, the commenters believe that it is not the best use of resources to offer the benefits to the entire membership; rather, the additional benefits should be focused on those who could most benefit from these additional resources.

Response: We will further consider such issues as part of the development of any future proposals to waive payment or other program rules. As MA plans are governed by different statutory requirements, we would need to make a separate, independent determination as to whether it is either possible or appropriate to make any changes to the requirements governing supplemental benefits under the MA program.

Comment: A commenter requested that future consideration of waivers should go through the notice and comment and rulemaking process.

Response: We agree.

Comment: A commenter stated that ACOs would need assurance that they are legally protected for their use of such waivers of payment or program rules, which may require additional coordination between CMS and the Department of Health and Human Services Office of the Inspector General.

Response: We are unclear about the commenter’s concern. We note that in developing the Shared Savings Program, and in response to stakeholder suggestions, we continue to work closely with agencies across the federal

government, including the HHS Office of the Inspector General. With respect to the commenter's concerns about legal protection for the use of waivers, any legal liability associated with the payment and program rule waivers under part 425 will depend on the particular facts and circumstances. Parties are encouraged to consult legal counsel as needed.

FINAL ACTION: We are adopting a new provision at § 425.612 of the regulations to provide for a waiver of the SNF 3-day rule for ACOs that participate in Track 3. Specifically, we will waive the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to the provision of Medicare covered post-hospital extended care services for beneficiaries that are prospectively assigned to ACOs that participate in Track 3. We will refer to this waiver and any payment or program rule waivers we establish in the future under the Shared Savings Program as being waivers under part 425. The waiver of the SNF 3-day rule under part 425 will allow for Medicare payment for otherwise covered SNF services when ACO providers/suppliers participating in eligible Track 3 ACOs admit an eligible prospectively assigned beneficiary to an eligible SNF without a 3 day prior inpatient hospitalization. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services shall continue to apply. This waiver will be effective on or after January 1, 2017, and all ACOs participating under Track 3 or applying to participate under Track 3 will be eligible to apply for the waiver.

Currently, our regulations at § 425.10 state that the regulations under part 425 must not be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare. Because the SNF 3-Day waiver modified certain coverage determinations, we are making a conform changes to § 425.10 of the regulations to add "except as permitted under section 1899(f) of the Act." For purposes of this waiver, an eligible ACO under the Shared Savings Program is an ACO that has elected to participate in Track 3 and has been approved by CMS as having demonstrated that it has the capacity to identify and manage patients who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3 days.

Finally, we will conduct further development and testing of other selected waivers through the CMS Innovation Center prior to deciding

whether it is necessary to incorporate such waivers in the Shared Savings Program. We intend to initially focus on further development and testing of a waiver of the billing and payment requirements for telehealth services through the Next Generation ACO Model (see the CMS Web site at: <http://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/>, page 22). We anticipate a telehealth waiver being available to ACOs no earlier than January 1, 2017, after notice and comment and rulemaking.

b. Other Options for Improving the Transition to Two-Sided Performance-Based Risk Arrangements

In the proposed rule, we also solicited comment on other options that could be implemented independent of waiver authority (79 FR 72826 through 72831) to support ACO efforts to increase quality and decrease costs under two-sided performance-based risk arrangements. They are as follows:

(1) Beneficiary Attestation

Under 1899(c) of the Act, beneficiaries are required to be assigned to an ACO participating in the Shared Savings Program based on the beneficiary's utilization of primary care services rendered by physicians participating in the ACO. Thus, beneficiary choice, as indicated by their utilization of primary care service furnished by physicians that are ACO professionals in the ACO, determines beneficiary assignment to an ACO under the Shared Savings Program.

In developing the policies for the November 2011 final rule, it was our intent to incentivize ACOs to redesign care processes and improve the health care system for all FFS beneficiaries and not create an incentive to treat some FFS beneficiaries preferentially or create inequalities in the care provided to FFS beneficiaries. We developed a hybrid approach where ACOs are given up-front information about their fee-for-service beneficiary population to help refine their care coordination activities, but are assessed at the end of each year based on beneficiaries that received a plurality of their primary care from ACO professionals during the performance year. We called this assignment method preliminary prospective assignment with retrospective reconciliation. Medicare FFS beneficiaries do not enroll in the Shared Savings Program, and they retain the right to seek treatment from any Medicare-enrolled provider of their choosing. No exclusions or restrictions based on health conditions or similar factors are applied in the assignment of Medicare

FFS beneficiaries. We adopted this policy because we believed that the methodology would balance beneficiary freedom to choose providers under FFS Medicare with the ACO's desire to have information about the FFS beneficiaries that were likely to be assigned at the end of the performance year.

Patient advocacy groups and ACOs have expressed interest in and support for enhancing claims-based assignment of beneficiaries to ACOs by taking into account beneficiary attestation regarding the provider that they consider to be responsible for coordinating their overall care. Stakeholders believe that incorporating this information and giving beneficiaries the opportunity to voluntarily "align" with the ACO in which their primary healthcare provider participates will improve the patient-centeredness of the assignment methodology.

To begin to address these concerns, we began conducting a test of beneficiary attestation in the Pioneer ACO Model for the 2015 performance year. Specifically, the Innovation Center designed a test in which beneficiaries were asked to confirm whether or not a listed provider or supplier is their "main doctor." Beneficiaries who confirmed a care relationship with the provider/supplier listed on the form and met all other eligibility criteria for alignment are aligned to the Pioneer ACO for the following performance year, regardless of whether or not the practitioners participating in the Pioneer ACO render the plurality of the beneficiary's primary care services during the alignment year. Additional testing in the future is planned under the Pioneer ACO Model and the Next Generation ACO Model that will build upon lessons learned from this initial test and in which we will seek to enhance the meaningfulness of dialogue between beneficiaries and their providers regarding the nature of the care relationship.

Although we did not make any specific proposals related to beneficiary attestation, we welcomed comments on whether it would be appropriate to offer a beneficiary attestation process to ACOs that choose to participate in the Shared Savings Program under two-sided risk financial arrangements. We noted that if we were to offer a beneficiary attestation process for ACOs that choose to participate in the Shared Savings Program under two-sided risk financial arrangements, we would anticipate implementing this beneficiary attestation in a manner consistent with the beneficiary attestation policy tested under the Pioneer ACO Model for the 2015 performance year. We sought

comment on a wide variety of policy and operational issues related to beneficiary attestation.

In connection with any implementation of beneficiary attestation, we also indicated that we would revise our regulations as necessary to protect beneficiaries from undue coercion or influence in connection with whether they choose to attest or not. We noted that beneficiary attestation is not intended to be used as a mechanism for ACOs (or ACO participants, ACO providers/suppliers, ACO professionals or others) to target potentially lucrative beneficiaries or avoid those less likely to produce savings. Further, we stated that we did not believe ACOs or others should be permitted to offer gifts or other inducements to beneficiaries, nor should they be allowed to withhold or threaten to withhold services, for the purposes of coercing or influencing their alignment decisions. However, we would not prohibit an ACO or its ACO participants and ACO providers/suppliers from providing a beneficiary with accurate descriptive information about the potential patient care benefits of aligning with an ACO. We solicited comment on these issues.

We received the following comments:

Comments: Most commenters supported beneficiary attestation for all tracks. Some commenters requested that we revise the assignment rules to permit (but not require) beneficiaries to elect to attribute themselves to a particular ACO or ACO physician. These commenters stated that they believe the most accurate method of assigning a beneficiary to a provider is based on the beneficiary's active selection and objected to the statutory requirement that a beneficiary be assigned to an ACO based on his/her utilization of primary care services furnished by physicians participating in the ACO. Some commenters supported beneficiary attestation only for ACOs participating in a two-sided performance-based risk model and further suggested that, unlike the Pioneer pilot, the attestation process should be available to all such patients, not just those previously assigned to the ACO.

Some commenters opposed beneficiary attestation or expressed significant concerns with it. These commenters stated that absent extensive beneficiary education (which has not yet occurred) beneficiary attestation may be premature. Some stated that while this policy may be appealing, more analysis is needed at this time to fully understand how it could be operationalized in a still-evolving national program. Other commenters

questioned what purpose beneficiary attestation would serve and why it is under consideration at all, given that it may open the door to marketing abuses by ACOs.

Response: We agree with commenters who recommended that we implement a policy to revise the beneficiary assignment methodology to permit beneficiaries to indicate who they believe is the "main doctor" responsible for their care coordination. We anticipate that a voluntary alignment approach that incorporates beneficiary preferences to supplement the current claims-based beneficiary assignment process could help mitigate fluctuations in assigned beneficiary populations. As explained in section II.F.3.(b).(4). of this final rule, such beneficiary attestation could be considered prior to applying the other assignment rules for assigning beneficiaries to an ACO.

We further believe this method would be consistent with the statutory requirement that a beneficiary be assigned to an ACO on the basis of primary care services rendered by physicians because the beneficiaries eligible for assignment under an approach similar to the one used in the Pioneer ACO Model for performance year 2015 would be those that were previously assigned based on an analysis of the ACO's claims for primary care services, including the requirement that the beneficiary have received at least one primary care service from a physician who is an ACO professional in the ACO.

However, based on our recent experiences with similar approaches under the Pioneer ACO Model, we also agree with commenters who believe that additional development and testing of the beneficiary attestation approach is necessary before it can be incorporated into the Shared Savings Program. We note that through the Next Generation ACO Model (see the CMS Web site at <http://innovation.cms.gov/Files/x/nextgenacorfa.pdf> pages 18 through 20), CMS will offer beneficiaries an opportunity to become aligned to Next Generation ACOs voluntarily as an addition to claims-based alignment. Next Generation ACOs may offer currently and previously aligned beneficiaries the option to confirm or deny their care relationships with specific Next Generation Providers/Suppliers. These decisions will take effect in alignment for the subsequent year. A beneficiary who completes the voluntary alignment process will have the option to reverse that decision or change the identified provider prior to development of the ACO's alignment list. The confirmation of a care

relationship through the voluntary alignment process will supersede claims-based attribution. For example, beneficiaries who indicate a Next Generation provider/supplier as their main care provider will be aligned with the ACO, even if claims-based alignment would not result in alignment. In later years of the Next Generation ACO Model, CMS may refine the voluntary alignment policies as follows:

- Make alignment accessible to a broader set of Medicare beneficiaries, regardless of current or previous alignment with an ACO.
- Include affirmation of a general care relationship between beneficiaries and ACOs instead of between beneficiaries and specific providers.
- Allow beneficiaries to opt out of alignment to a particular ACO in addition to opting into alignment.

Therefore, we intend to carefully consider the results of further testing of beneficiary attestation under the Pioneer ACO Model and the Next Generation ACO Model for the 2016 performance year and expect to propose to implement beneficiary attestation for purposes of beneficiary assignment under the Shared Savings Program beginning January 1, 2017. We expect to propose a beneficiary attestation policy for the Shared Savings Program in the 2017 PFS rulemaking. This timeline will allow for further development and testing of this approach through the Pioneer ACO Model and further development of this approach through the Next Generation ACO Model. Initially, until we gain additional operational experience, we anticipate limiting this beneficiary attestation process to ACOs that choose Tracks 2 or 3 as an additional incentive for ACOs willing to take on increased risk. This approach will also allow for further development of the operational details, and will provide an opportunity for additional public input. We will also have additional time to learn from CMS Innovation Center models that are testing beneficiary attestation, specifically the Pioneer ACO Model and the Next Generation ACO Model.

Comment: Some commenters provided suggestions on specific operational details regarding implementing beneficiary attestation under the Shared Savings Program. Some commenters suggested that the attestation method being tested under the Pioneer ACO Model is burdensome and that CMS should develop a system in which patients could select an ACO via 1-800 Medicare or Medicare.gov. A commenter indicated that the attestation should be based on the patient's

selection of their primary care provider, rather than the name of an ACO, since most patients will not be familiar with the name of their provider's ACO. The commenter suggested that ACOs be responsible for informing patients of the option to attest to a care relationship with an ACO, but that CMS should administer the process and maintain information on patient choices and help assure that beneficiary communications about attestation and opting in or opting out will be consistent and appropriate. A commenter suggested that the patient attestation and beneficiary opt-out processes only occur during the first three months of each performance year. A commenter's suggestions for making performance-based risk more attractive included rapid development and implementation of a user friendly beneficiary and provider portal similar to those used in the commercial insurance market that would be maintained by CMS and accessible to beneficiaries, ACOs and providers. The commenter explained beneficiaries would be allowed to select their ACO or primary care provider in more "real time," and the providers could in turn "pull" the information from the portal. The commenter believes that CMS is currently using archaic means to transfer information to the ACOs participating in the Shared Savings Program, with cumbersome data feeds that require manpower and expense to manipulate.

Response: We appreciate receiving the many helpful suggestions, which we will further consider in the development of any future proposals to incorporate beneficiary attestation as part of the Shared Savings Program.

FINAL ACTION: We expect to propose to implement beneficiary attestation for purposes of beneficiary assignment under the Shared Savings Program beginning January 1, 2017, in the 2017 PFS rulemaking. This timeline will allow for further development and testing of this approach through the Pioneer ACO Model and the Next Generation ACO Model and development of appropriate safeguards against abusive or coercive marketing associated with beneficiary attestation. Initially, until we gain additional operational experience, we anticipate limiting the beneficiary attestation process to ACOs participating under Tracks 2 or 3.

(2) Solicitation of Comment on a Step-Wise Progression for ACOs To Take on Performance-Based Risk

Under the current Shared Savings Program rules, an ACO may not include an entity on its list of ACO participants

unless all ACO providers/suppliers billing through the entity's Medicare-enrolled TIN have agreed to participate in the program and comply with the program rules (see discussion in section II.B. of this final rule). Furthermore, it is not possible under our current regulations for some ACO providers/suppliers to participate in Track 1, while other ACO providers/suppliers that may be more ready to accept performance-based risk participate under Track 2. In the proposed rule, we noted that some stakeholders have commented that requiring all ACO providers/suppliers billing through an ACO participant TIN to participate in the same risk track could deter some ACOs from entering higher risk arrangements (Tracks 2 or 3) if they do not believe that all of the ACO providers/suppliers billing through a given ACO participant TIN are prepared to operate under high levels of risk. Conversely, we have heard from other stakeholders that requiring all ACO providers/suppliers billing through an ACO participant TIN to enter the same risk track can motivate an organization to work toward a common performance goal and implement uniform care processes that streamline patient care within and between various sites of care. We believe that the program works best when the incentives within an organization are aligned among all providers and suppliers in that organization.

We did not propose to change our regulations in order to allow providers and suppliers billing through the same ACO participant TIN to participate in different tracks under the Shared Savings Program. However, given our policy objectives to encourage ACOs to redesign their care processes and move to increasing levels of financial risk, we expressed our interest in stakeholder opinion on this issue and sought comment on what options the program might consider in the future to encourage organizations to participate in the program while permitting the providers and suppliers within that organization to accept varying degrees of risk. In particular, we sought stakeholders' input on the advantages and disadvantages of allowing Shared Savings Program ACOs that wish to enter a track with increased risk to split their ACO participants into different tracks or split ACO providers/suppliers billing through a given Medicare-enrolled TIN so that a subset participate in a track that offers a higher sharing rate in exchange for taking on a greater degree of performance-based risk, while

the remainder participate in a lower risk track.

Comments: We received a modest number of comments on this issue and the commenters were mixed on their views. Some commenters supported permitting "split TINs", stating this may increase the number of providers willing to join ACOs but who may not be ready for assuming risk and may allow "single TIN" entities or large organizations such as academic medical centers and their faculty practice plans to enter the program with a subset of their providers—primary care providers, for example—rather than sitting out until they confidently believe that the whole system is ready to participate. Some suggested modifications should be made such as dividing TINs geographically so that one TIN may participate in multiple ACOs.

Some other commenters were strongly opposed to permitting ACOs to split ACO providers/suppliers or ACO participant TINs between risk tracks. Such commenters stated they believe the concept and practice of accountability and transforming the care of a population should be universal throughout the ACO, and not segmented within the ACO. They expressed concerns that such a policy would open up the risk of gaming, both through selection of providers for participation in certain tracks and adverse selection of patients depending on an ACO's strategy of whether to assume one-sided or two-sided risk. Others expressed concern that such policies could lead to cherry picking of beneficiaries to achieve higher incentive payments without real quality improvement. Others raised concerns that this policy would be too complex and burdensome for both ACOs and CMS.

Response: We appreciate the comments on this issue. At this time, we are persuaded by commenters who raised concerns about operational complexity for ACOs and CMS. We also agree there could be significant risks for "cherry picking" of beneficiaries to achieve higher incentive payments without real quality improvement. Such strategies could be detrimental to the progress ACOs have made to date. Most ACOs are learning from their initial experiences in the Shared Savings Program, and many have been successful in transforming the care of their entire FFS beneficiary population while accepting accountability for all assigned patients. However, we appreciate the flexibility that could be afforded to ACOs if a methodology could be developed that would permit ACOs to split ACO participants or ACO providers/suppliers into two different

risk tracks. Under such a model, ACOs could progressively move providers participating in their organizations into risk in a step-wise fashion. Therefore, we are interested in exploring operational processes that could permit such a design while also ensuring

appropriate beneficiary protections. We intend to continue considering this issue and may revisit it in future rulemaking as infrastructure evolves to support this new alternative.

FINAL ACTION: We will explore operational processes to develop a methodology that would permit ACOs

to split ACO participants or ACO providers/suppliers into two different risk tracks while also ensuring appropriate beneficiary protections. We may revisit this approach in future rulemaking as infrastructure evolves to support this new alternative.

TABLE 8—COMPARISON OF ONE- AND TWO-SIDED PERFORMANCE-BASED RISK MODELS BY TRACK

Issue	Track 1: One-Sided Risk Model		Tracks 2 and 3: Two-Sided Risk Models		
	Current	Final	Current Track 2	Final	New Track 3
Transition to Two-Sided Model.	First agreement period under one-sided model. Subsequent agreement periods under two-sided model.	Remove requirement to transition to two-sided model for a second agreement period.	ACOs may elect Track 2 without completing a prior agreement period under a one-sided model. Once elected, ACOs cannot go into Track 1 for subsequent agreement periods.	No change	Same as Track 2.
Assignment	Preliminary prospective assignment for reports; retrospective assignment for financial reconciliation.	No change	Preliminary prospective assignment for reports; retrospective assignment for financial reconciliation.	No change	Prospective assignment for reports, quality reporting and financial reconciliation.
Benchmark	Reset at the start of each agreement period.	Modifications to rebasing methodology for an ACO's second or subsequent agreement period: equal weighting benchmark years, and including a per capita amount reflecting the ACO's financial and quality performance during prior agreement period.	Same as Track 1	Same as Track 1.	Same as Tracks 1 and 2.
Adjustments for health status and demographic changes.	Historical benchmark expenditures adjusted based on CMS-HCC model. Updated historical benchmark adjusted relative to the risk profile of the performance year. Performance year: newly assigned beneficiaries adjusted using CMS-HCC model; continuously assigned beneficiaries adjusted using demographic factors alone unless CMS-HCC risk scores result in a lower risk score.	No change	Same as Track 1	No change	Same as Tracks 1 and 2.
Benchmark and Performance year Expenditures.	Payment amounts included in Parts A and B FFS claims using a 3-month claims run out with a completion factor. (i) excluding IME and DSH payments. (ii) including individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.	No change	Same as Track 1	No change	Same as Tracks 1 and 2.

TABLE 8—COMPARISON OF ONE- AND TWO-SIDED PERFORMANCE-BASED RISK MODELS BY TRACK—Continued

Issue	Track 1: One-Sided Risk Model		Tracks 2 and 3: Two-Sided Risk Models		
	Current	Final	Current Track 2	Final	New Track 3
Final Sharing Rate.	Up to 50% based on quality performance.	No change. (Up to 50% based on quality performance for second agreement period under the one-sided model).	Up to 60% based on quality performance.	No change	Up to 75% based on quality performance.
Minimum Savings Rate.	2.0% to 3.9% depending on number of assigned beneficiaries.	No change	Fixed 2.0%	Choice of symmetrical MSR/MLR: (i) no MSR/MLR; (ii) symmetrical MSR/MLR in 0.5% increment between 0.5% - 2.0%; (iii) symmetrical MSR/MLR to vary based upon number of assigned beneficiaries (as in Track 1).	Same as Track 2.
Minimum Loss Rate.	Not applicable	No change	Fixed 2.0%	See options under MSR.	See options under MSR.
Performance Payment Limit.	10%	No change	15%	No change	20%.
Shared Savings ..	First dollar sharing once MSR is met or exceeded..	No change	Same as Track 1	No change	Same as Tracks 1 and 2.
Shared Loss Rate.	Not applicable	No change	One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate may not be less than 40% or exceed 60%.	No change	One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate may not be less than 40% or exceed 75%.
Loss Sharing Limit.	Not applicable	No change	Limit on the amount of losses to be shared phases in over 3-years starting at 5% in year 1; 7.5% in year 2; and 10% in year 3 and any subsequent year. Losses in excess of the annual limit would not be shared.	No change	15%. Losses in excess of the annual limit would not be shared.
Payment and Program Rule Waivers under Part 425.	Not applicable	No change	Not applicable	No change	ACOs may elect to apply for a waiver of the SNF 3-Day Rule.

G. Additional Program Requirements and Beneficiary Protections

1. Background

Section 1899(a)(1)(A) of the Act authorizes the Secretary to specify criteria that ACOs must satisfy in order to be eligible to participate in the

Shared Savings Program. In the November 2011 final rule, we finalized policies regarding how ACOs will be monitored with respect to program requirements and what actions will be taken against ACOs that are not in compliance with the requirements of the Shared Savings Program.

Based on our initial experience with the Shared Savings Program, we proposed several refinements and clarifications to our policies on the following:

- Public reporting (§ 425.308).
- Termination of the participation agreement (§§ 425.218 and 425.220).

- Enforcement of ACO compliance with quality performance standards (§ 425.316(c)).
- Reconsideration review procedures (§§ 425.802 and 425.804).

2. Public Reporting and Transparency

a. Overview

Section 1899 of the Act sets forth a number of requirements for ACOs. Section 1899(b)(2)(H) of the Act requires ACOs to demonstrate that they meet patient-centeredness criteria specified by the Secretary. We believe that one important aspect of patient-centeredness is patient engagement and transparency. Increasingly, transparency of information in the health care sector is seen as a means to help patients become more active in their health care choices and to generate feedback that may improve the quality of care and lower the cost of care. In addition, transparency may improve oversight and program integrity. Public reporting also supports the mandate for ACOs to be willing to “become accountable for the quality, cost, and overall care” of the Medicare beneficiaries assigned to them. Reports on ACO quality and cost performance hold ACOs accountable and contribute to the dialogue on how to drive improvement and innovation in health care. Public reporting of ACO cost and quality data may improve a beneficiary’s ability to make informed health care choices and facilitate an ACO’s ability to improve the quality and efficiency of its care.

Therefore, for these reasons, which are described in more detail in the November 2011 final rule, we finalized requirements specified at § 425.308 that ACOs must make certain information publicly available. Since publication of the final rule, minor updates were made to § 425.308(e) in the 2013 PFS final rule with comment period (77 FR 69164 through 69170) and in the 2015 PFS final rule with comment period (79 FR 67769). For purposes of the Shared Savings Program, each ACO is currently required at § 425.308 to publicly report certain organizational and other information. Currently, we recommend that ACOs publicly report the specified information in a standardized format that we have made available to ACOs through guidance at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Public-Reporting-Guidance.pdf>. Our guidance recommends that ACOs report the required information on a Web site that complies with the marketing requirements set forth at § 425.310. Because Web pages used to

publicly report the information specified in § 425.308 constitute “marketing materials and activities,” as defined at § 425.20, any changes to such Web pages must be submitted for our review in accordance with § 425.310. Thus, if an ACO changes any of the information on its public reporting Web page, such as adding an ACO participant or replacing a member of the governing body, the ACO must submit its Web page to us for marketing review. Because we believe this policy creates undue burden on the ACO as well as on CMS, we proposed some refinements to the requirements related to public reporting and transparency.

b. Proposals

In the December 2014 proposed rule, we proposed to modify the public reporting requirements set forth at § 425.308. In § 425.308(a), we proposed to require that each ACO maintain a dedicated Web page on which the ACO must publicly report specified information. In addition, we proposed that an ACO must report to us the address of the Web page on which it discloses the information set forth in § 425.308 and apprise us of changes to that Web site address in the form and manner specified by CMS. We solicited comment on when an ACO should be required to inform us of such changes (for example, within 30 days after the change has occurred).

Additionally, we noted that existing § 425.308(b) requires ACOs to report certain information in a standardized format specified by CMS. Currently, our guidance sets forth a standardized format (template) that ACOs must use so that ACOs report information uniformly. We proposed in § 425.308(c) that information reported on an ACO’s public reporting Web page in compliance with the requirements of the standardized format specified by CMS, (that is, through use of the template) would not be subject to marketing review and approval under § 425.310.

We also proposed to make a few changes to the information that must be publicly reported. In § 425.308(b), we proposed to add two categories of organizational information that must be publicly reported. First, we proposed to add a requirement at § 425.308(b)(3)(iv) that ACOs publicly identify key clinical and administrative leaders within their organization as part of the public reporting requirements. Second, we proposed to add a provision at § 425.308(b)(3)(vi) requiring ACOs to publicly report the types of ACO participants or combinations of ACO participants, as listed in § 425.102(a), that form the ACO. We believe it would

be helpful for the public to have a better understanding of the types of ACO participants or combinations of ACO participants that are listed at § 425.102(a) that have joined to form the ACO. We noted that stakeholders have requested information about the composition of ACOs and that publicly reporting the types and combinations of ACO participants would assist stakeholders in understanding the composition of ACOs.

In addition, we proposed at § 425.308(b)(5) to require each ACO to publicly report its performance on all quality measures used to assess the quality of care furnished by the ACO. As explained in more detail in the December 2014 proposed rule, we agreed with the comments made by stakeholders that requiring an ACO to publicly report its performance on all quality measures (as defined at § 425.20) would provide a more accurate picture of the ACO’s performance. We also noted a technical modification to our rules. Currently, we require ACOs to report the amount of any “shared savings performance payment” (§ 425.308(d)(1)). However, to conform this provision to the definition of “shared savings” at § 425.20, we proposed to remove the term “performance payment” from the phrase and insert the new language at revised § 425.308(b)(4)(i).

Finally, we noted in the December 2014 proposed rule that, for purposes of program transparency, we find it useful to publicly post certain information about ACOs. Therefore, we proposed at § 425.308(d) to post certain ACO-specific information, including information that the ACO is required to publicly report under § 425.308, as necessary to support program goals and transparency. We solicited comment on what other information should be published on our Web site. Because proposed § 425.308(d) encompasses our ability to publicly report ACO performance on all quality measures, we proposed to remove § 425.308(e) or reserve it for future use.

Comment: Many commenters expressed support for our public reporting and transparency requirements, stating that they enable beneficiaries to make informed decisions and reduce fraud and abuse. Commenters also noted that transparency and public reporting can spur innovation in quality and efficiency. Stakeholders also supported implementation of these policies in a way that would not impose undue burdens for ACOs.

Response: We appreciate stakeholder support for public reporting and

transparency requirements. We agree that such transparency can improve beneficiary engagement, reduce fraud and abuse, and encourage organizations to improve quality and efficiency of care. We believe that many of the policies proposed will reduce burden on ACOs and CMS because, for example, the ACO will have a pre-approved format for reporting the required information and such changes will not be subject to marketing review.

Comment: A few commenters specifically addressed our proposal to require ACOs to maintain a dedicated Web page and report the address to us. These commenters encouraged CMS to provide ACO web addresses through the CMS Web site and suggested that ACOs notify CMS of Web page address changes and other changes within a reasonable time frame to permit CMS compliance review.

Several commenters specifically supported our proposal to require ACOs to use a standardized template to publicly report required information and supported our proposal to not require marketing review of information disclosed using a standardized template. Commenters agreed that our policies would ensure consistent practice by all ACOs, make information uniformly available to the public, and provide some relief from marketing reviews. Some commenters stressed the importance of ensuring that ACOs post accurate, CMS-validated information on their Web sites. A commenter stated that the marketing review in general is overly burdensome and urged CMS to review the current marketing requirements. Additionally, a few commenters suggested that we ensure that the required template is clear and manageable by soliciting input from stakeholders such as ACOs, beneficiaries, and others on draft templates prior to implementation.

Some commenters suggested that use of the template should be optional, in which case changes to information posted by ACOs choosing not to use the template would remain subject to marketing review. A commenter specifically opposed the use of a template, stating that its use would stifle creativity and limit available data.

Response: We appreciate commenters' support for our proposals to require an ACO to maintain a dedicated Web page and report this web address to us. We also appreciate support for ACOs to use a standardized template which will be exempt from marketing review. Because we believe it is important for this information to be uniformly available to the public, we will not permit ACOs to diverge from the template required by

CMS. We note that although information reported using the template will be exempt from the marketing review requirements, such information will continue to be subject to compliance audit and review and therefore must be accurately maintained. Furthermore, we may consider whether our marketing review requirements should be revised in future rulemaking. We also note that if an ACO wants to report more information than required in the template, the ACO may submit the additional information through marketing review if such information constitutes "marketing materials and activities" as defined at § 425.20. Finally, we invite ACO input through established modes of communication with CMS on templates that are developed and intend to take such comments into consideration when revising and updating the template.

Comment: A few comments directly addressed our proposals for modifying the kind of information ACOs must make publicly available. A commenter noted that these additional requirements will facilitate shared learning among ACOs and stakeholders. Another commenter stated that it would support reporting additional organizational information if CMS defines terms and provides clear guidance on what needs to be posted. Several commenters suggested requiring ACOs to publicly report additional information, such as disclosure of its parent corporation or the amount of shared savings that participating physicians in the ACO receive. A commenter encouraged CMS to establish a requirement for ACOs to report their HIT and interoperability capabilities. Another commenter recommended that we permit flexibility for ACOs to supplement the required publicly posted information with additional metrics.

Response: We are finalizing our proposals to modify the information ACOs are required to publicly report. Specifically, in addition to the information the ACO is currently required to report, we will require ACOs to publicly identify key clinical and administrative leaders within their organizations and the types of ACO participants or combinations of ACO participants that are listed at § 425.102(a) that have joined to form the ACO. We believe these minor additions will improve public understanding of individual ACOs as well as foster shared learning. Additionally, we will provide further guidance to help ACOs clearly understand what information they must make publicly available. We appreciate the suggestions for reporting additional ACO-specific information, and believe it

could be appropriate to require ACOs to make this type of information public. However, we believe it will be appropriate to give ACOs and other stakeholders the opportunity to provide input on what additional information ACOs should be required to make public and whether there are other factors that should be considered before adopting additional public reporting requirements. Accordingly, we expect to consider these suggestions further in future rulemaking.

Additionally, we note that ACOs are currently permitted to maintain and post additional metrics on their own public Web sites. However, such information is subject to marketing review.

Comment: A few commenters supported the posting of ACO quality measure results publicly in general. However, they opposed duplication of effort. Specifically, commenters disagreed with our proposal to require ACOs to report on their Web sites the same information that would be posted by CMS, for example, on Physician Compare, stating this would be redundant.

Several commenters supported the proposal and recommended that ACO-specific information be posted at a "central CMS location."

A few commenters recommended that we post additional ACO-specific information, such as ACO and commercial cost information or additional quality information, such as medical errors and infection rates. A few commenters provided specific recommendations related to quality data reporting, specifically, that CMS post quality measure results at the provider level. A commenter stated that ACO measures should be reported at the ACO or ACO participant level, but not at the ACO provider/supplier level. Another commenter urged CMS to provide thorough explanations of measures and rankings to ensure the public understands ACO quality performance data.

Some commenters expressed the need for public reporting uniformity across CMS and ACO Web sites, and a commenter suggested that ACO information be posted on a state's department of public health Web site.

Response: We are finalizing our proposal to require ACOs to report all quality measure data on their public Web sites. Although this policy may appear redundant or duplicative, we believe it is important to provide stakeholders multiple ways to retrieve information about specific ACOs and the program as a whole. For instance, the public can access specific and

updated information about a particular ACO by going to ACO-specific Web sites which will likely be updated more frequently than the CMS Web site, which provides annual information (such as the results of quality reporting) for all ACOs in one location to allow for comparison between ACOs. We note that we do not believe we have the authority to require posting of ACO information on states' department of public health Web sites. However, we anticipate posting all ACO-specific information on a central, easily accessible Web site.

For the reasons stated previously, and to ensure accuracy and transparency of ACO-specific information, we are also finalizing our proposal to post ACO-specific data as necessary to support program goals.

FINAL ACTION: We are finalizing these policies as proposed. These policies are reflected in § 425.308. Specifically, we require that each ACO maintain a dedicated Web page on which the ACO must publicly report the information listed in paragraph (b) using a template specified by CMS. We are making a technical correction at § 425.308(b) to add the word "publicly" to clarify that the information reported using the template must be publicly available. Each ACO must report to us the address of the Web page on which it discloses the information set forth in § 425.308 and apprise us of changes to that Web site address in the form and manner specified by CMS in operational guidance. Additionally, information reported on an ACO's public reporting Web page in the standardized format specified by CMS will not be subject to marketing review and approval under § 425.310.

We are also finalizing our proposal to revise the information that must be publicly reported. Specifically, we are requiring at § 425.308(b)(3)(iv) that ACOs publicly identify and list the key clinical and administrative leaders within their organization. Additionally, we are adding a provision at § 425.308(b)(3)(vi) to require ACOs to publicly report the types of ACO participants or combinations of ACO participants, as listed in § 425.102(a), that form the ACO.

We are finalizing the modification to § 425.308(b)(5) as proposed to require each ACO to publicly report its performance on all quality measures as well as the technical modification to § 425.308(d)(1) to remove the term "performance payment" and insert revised language at § 425.308(b)(4)(i). Additionally, as discussed in more detail in section II.F.7. of this final rule, we will include the requirement for

ACOs to publicly report their use of any waivers under § 425.612, if applicable.

Lastly, we are finalizing § 425.308(d), which will allow CMS to publicly report ACO-specific information, including information the ACO is required to publicly report under § 425.308, as necessary to support program goals and transparency. Because § 425.308(d) encompasses our ability to publicly report ACO performance on all quality measures, we are finalizing our proposal to remove § 425.308(e).

3. Terminating Program Participation

a. Overview

Section 425.218 of our regulations sets forth the grounds for terminating an ACO for failure to comply with the requirements of the Shared Savings Program (§ 425.218(a)). For example, an ACO's or ACO participant's failure to notify beneficiaries of their provider's participation in the program as required under § 425.312 would constitute grounds for terminating the ACO. In addition, we may terminate an ACO for a number of other violations, such as those related to certain fraud and abuse laws, the antitrust laws, or other applicable Medicare laws and regulations relevant to ACO operations, or if certain sanctions have been imposed on the ACO by an accrediting organization or a federal, state or local government agency (§ 425.218(b)).

Prior to termination, we may take interim steps such as issuing the ACO a warning notice or placing the ACO on a corrective action plan (CAP) (§ 425.216). However, we reserved the right to immediately terminate a participation agreement if necessary (§ 425.218(c)). We notify the ACO in writing if the decision is made to terminate the participation agreement.

Under § 425.220, an ACO may voluntarily terminate its participation agreement. Such an ACO is required to provide CMS and all of its ACO participants with 60 days advance written notice of its decision to terminate its participation in the Shared Savings Program. An ACO is not required to notify beneficiaries of the ACO's decision to terminate from the Shared Savings Program. Under current regulations, an ACO that terminates its participation agreement before expiration of the participation agreement does not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement (§ 425.220(b)). This is because an ACO that terminates its participation agreement during a performance year will have failed to complete the entire

performance year. Therefore, it will have failed to meet the requirements for shared savings.

b. Proposed Revisions

We proposed several modifications to the regulations related to termination of a participation agreement. First, we proposed to permit termination for failure to timely comply with requests for documents and other information and for submitting false or fraudulent data. In addition, we proposed to add a new regulation at § 425.221 requiring ACOs to implement certain close-out procedures upon termination and nonrenewal. Finally, we proposed to address in new § 425.221 the payment consequences upon termination of a participation agreement.

(1) Grounds for Termination

First, at § 425.218(b) we proposed to modify the grounds for termination to specifically include the failure to comply with CMS requests for submission of documents and other information by the CMS specified deadline. At times, we may request certain information from the ACO in accordance with program rules. As explained in the December 2014 proposed rule, the submission of those documents by the specified due date is important for program operations. For example, we require each ACO to submit to us, on an annual basis, its list of ACO participants and their TINs (existing § 425.304 and proposed § 425.118). We explained that when ACOs do not submit these lists by the due date specified, it prevents us from applying the assignment methodology (which is dependent on having accurate lists of ACO participants for all ACOs) and impacts the timelines for the program, such as the calculation of the benchmarks for all ACOs. Missing such deadlines is very disruptive to the program and other ACOs. Therefore, we proposed to modify § 425.218(b) to permit termination of an ACO agreement for failure to comply with requests for information and documentation by the due date specified by CMS.

Additionally, under § 425.302, an individual with the authority to legally bind the individual or entity submitting data or information to CMS must certify the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge and belief. However, circumstances could arise in which the data and information submitted (for example, data submitted through the CMS web interface used to determine an ACO's quality performance) was falsified or

fraudulent. Submission of false or fraudulent data is a serious offense that could harm the Shared Savings Program; for example, it could impact the amount of shared savings calculated for the ACO and cause CMS to overpay the ACO. We proposed to modify § 425.218(b) to permit termination of an ACO agreement for submission of false or fraudulent data. We note that ACOs are obligated to repay shared savings payments to which they are not entitled, including, by way of example only, any overpayment to the ACO based on the submission of false or fraudulent data.

(2) Close-Out Procedures and Payment Consequences of Early Termination

We proposed to add new § 425.221 to address close-out procedures and payment consequences of early termination. First, we believe it was important to establish an orderly close-out process when an ACO's participation agreement is terminated. Therefore, we proposed in § 425.221(a) that an ACO whose participation agreement is terminated prior to its expiration either voluntarily or by CMS must implement close-out procedures in a form, manner, and deadline specified by CMS. We proposed that these close-out procedures would address such issues as data sharing (such as data destruction), beneficiary notification (for example removal of marketing materials and ensuring beneficiary care is not interrupted), compliance with quality reporting, and record retention. We noted that the close-out procedures would also apply to those ACOs that have elected not to renew their agreements upon expiration of the participation agreement. We also proposed in § 425.221(a)(2) that any ACO that failed to complete the close-out procedures in the form and manner and by the deadline specified by CMS would not be eligible for shared savings. We solicited comments on other strategies that would ensure compliance with close-out procedures.

Second, we proposed in § 425.221(b) to address certain payment consequences of early termination. Currently under § 425.220(b), an ACO that voluntarily terminates its agreement at any time during a performance year will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement. However, stakeholders suggested that completion of the performance year, as part of an orderly close-out process, could be mutually beneficial to the ACO, its ACO participants and ACO providers/suppliers, and to CMS. Specifically, stakeholders suggested that an ACO

should be entitled to receive shared savings if the ACO completes a performance year through December 31 and satisfies all requirements for sharing in savings for that performance year (for example, the quality reporting for the performance year). Additionally, by completing quality reporting as part of the close-out process, the ACO participants would not be penalized by the ACO's decision to terminate its participation agreement. For example, eligible professionals that bill through the TIN of an ACO participant could satisfy the reporting requirement to avoid the downward payment adjustment under the PQRS in a subsequent year.

Therefore, we proposed in § 425.221(b) to permit an ACO whose participation agreement is voluntarily terminated by the ACO under § 425.220 to qualify for shared savings, if—

- The effective date of termination is December 31; and
- By a date specified by CMS, it completes its close-out process for the performance year in which the termination becomes effective.

In order to effectively manage this option in the case of voluntary termination, the ACO must specify in its termination notice, and CMS must approve, a termination effective date of December 31 for the current performance year. Because the proposed new provision at § 425.221 addressed the consequences of termination, including the payment consequences, we also proposed to make a conforming change to § 425.220 to remove paragraph (b) addressing the payment consequences of early termination.

We noted that under this proposal, the opportunity to share in savings for a performance year would not extend to ACOs that terminate their participation agreement with effective dates prior to December 31 or to ACOs that CMS terminates under § 425.218. Those ACOs that terminate prior to December 31 would not have completed the performance year and thus would not qualify for shared savings. ACOs terminated by CMS under § 425.218 would not qualify for shared savings irrespective of the termination date because maintaining eligibility to participate in the Shared Savings Program is a pre-requisite for sharing in savings (see §§ 425.604(c) and 425.606(c)). In such cases, we strongly encouraged ACOs to fulfill their obligations to their ACO participants and ACO providers/suppliers by reporting quality for the performance year in which it terminates so that their ACO participants and ACO providers/suppliers are not unduly penalized by

the ACO's decision. However, even if the ACO completes quality reporting on behalf of its ACO participants and ACO provider/suppliers, if the ACO terminates its participation midyear or is terminated by CMS under § 425.218 (prior to December 31), it would not be eligible to share in savings for the performance year. The ACO would not be eligible to share in savings because the ACO would not have satisfied all requirements for sharing in savings for that performance year.

Comment: A few commenters supported the proposals related to grounds for termination of an ACO, stating that it is important to ensure consistent practices by all participants. A commenter supported the proposal so long as ACOs would be provided reasonable timeframes to satisfy CMS requests.

Response: We agree that it is important to apply consistent practices across ACOs participating in the Shared Savings Program. The submission of documents by a specified due date is necessary for program operations. We believe that we have established reasonable timeframes for ACOs to satisfy such documentation requests, and we alert ACOs of deadlines well in advance through newsletters and other ACO communications. For example, we give ACOs at least 30 days to return the Certificate of Disposition for data destruction. Additionally, we allow ACOs to take up to 60 days to notify their participant TINs that the ACO is terminating its agreement with CMS. To date, ACOs have not expressed concern over these or other deadlines related to termination.

Comment: The few comments we received stated they supported our proposals regarding close-out procedures because of the clarity and certainty it provides for this aspect of the program. Several commenters supported our proposals regarding payment consequences of early termination. A commenter suggested that CMS provide an opportunity to negotiate certain close-out procedures without forfeiting shared savings if it poses no direct risks to beneficiaries. For example, the commenter stated that ACOs should be able to negotiate to adjust the timing of data destruction to correspond with established organizational timelines for such activities. Another commenter stated that ACOs should not be required to report quality measures to satisfy PQRS reporting on behalf of its eligible professionals that bill under the TIN of an ACO participant when the ACO terminates midyear. Another commenter stated that if unforeseen circumstances

prevent an ACO from completing the performance year, CMS should provide the ACO an opportunity to appeal the limitation against earning shared savings for that year.

Response: We appreciate the support for our proposals related to close-out procedures. The timely completion of all close-out procedures is mutually beneficial to the ACO, its ACO participants and ACO provider/suppliers, as well as CMS. We believe it is reasonable for an ACO to share in savings for a given performance year, provided it has satisfied all the requirements for obtaining a shared savings payment, including completion of the performance year and close-out procedures. The close-out procedures are particularly important because, for instance, they require the ACO to complete quality reporting after the completed performance year, adhere to data destruction requirements, and notify ACO participants, ACO providers/suppliers, and beneficiaries as necessary to ensure proper transfer of care. We also believe that requiring ACOs to complete close-out procedures in order to receive shared savings for their final performance year will result in timely and accurate completion of the ACO's final obligations after termination.

We will not provide ACOs that terminate in the middle of a performance year the opportunity to request an exception to or otherwise "appeal" the rule that prevents such ACOs from receiving shared savings. As we noted in the proposed rule, the opportunity to share in savings for a performance year will not extend to ACOs that terminate their participation agreement with effective dates prior to December 31 or to ACOs that CMS terminates under § 425.218 because the ACO will not have completed the requirements for sharing in savings for the performance year. Furthermore, our rule does not provide a methodology for calculating shared savings for partial year participation. Moreover, the determination of whether an ACO is eligible for shared savings is precluded from administrative and judicial review. Therefore, accommodating the commenter's request is beyond the scope of this rulemaking.

FINAL ACTION: We are finalizing our proposals related to terminating program participation. Specifically, we are finalizing our proposal to modify § 425.218(b) to permit termination of an ACO agreement for failure to comply with requests for information and documentation by the due date specified by CMS. Additionally, because we received no objections related to our

proposal to terminate an ACO agreement for submission of false or fraudulent data, we are finalizing our proposal to modify § 425.218(b). We note that ACOs are obligated to repay shared savings payments to which they are not entitled, including, by way of example only, any overpayment to the ACO based on the submission of false or fraudulent data.

We are also finalizing our proposal to add new § 425.221 to address close-out procedures and payment consequences of early termination. At new § 425.221(a), an ACO whose participation agreement is terminated prior to its expiration either voluntarily or by CMS must implement close-out procedures regarding the following in a form, manner, and deadline specified by CMS:

- Notice to ACO participants of termination.

- Record retention.

- Data sharing.

- Quality reporting.

- Beneficiary continuity of care.

The close-out procedures also apply to those ACOs that have elected not to renew their agreements upon expiration of the participation agreement. At § 425.221(a)(2), any ACO that fails to complete the close-out procedures in the form and manner and by the deadline specified by CMS will not be eligible for shared savings. At new § 425.221(b), an ACO whose participation agreement is voluntarily terminated by the ACO under § 425.220 will qualify for shared savings for the performance year during which the termination becomes effective, if—

- The effective date of termination is December 31;

- By a date specified by CMS, the ACO completes its close-out process for the performance year in which the termination becomes effective; or

- The ACO has satisfied the criteria for sharing in savings for the performance year.

In order to effectively manage this option, the ACO must specify in its termination notice, and CMS must approve, a termination effective date of December 31 for the current performance year. Because the proposed new provision at § 425.221 will address the consequences of termination, including the payment consequences, we will also finalize our proposal to make a conforming change to § 425.220 to remove paragraph (b) addressing the payment consequences of early termination. For the reasons specified in our proposed rule, the opportunity to share in savings for a performance year does not extend to an ACO that terminates its participation agreement

with an effective date prior to December 31 or to an ACO that CMS terminates under § 425.218.

4. Reconsideration Review Process

a. Overview

Under § 425.802(a), an ACO may appeal an initial determination that is not subject to the statutory preclusion on administrative or judicial review (see section 1899(g) of the Act). Specifically, the following determinations are not subject to administrative or judicial review:

- The specification of quality and performance standards under §§ 425.500 and 425.502.

- The assessment of the quality of care furnished by an ACO under the performance standards.

- The assignment of beneficiaries.
- The determination of whether the ACO is eligible for shared savings and the amount of such shared savings (including the determination of the estimated average per capita Medicare expenditures under the ACO for beneficiaries assigned to the ACO and the average benchmark for the ACO).

- The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under §§ 425.604 and 425.606.

- The termination of an ACO for failure to meet the quality performance standards.

Initial determinations that are not precluded from administrative or judicial review would include the denial of an ACO application or the involuntary termination of an ACO's participation agreement by CMS for reasons other than the ACO's failure to meet the quality performance standard.

Under § 425.802(a), an ACO may appeal an initial determination that is not prohibited from administrative or judicial review by requesting reconsideration review by a CMS official. The request for review must be submitted for receipt by CMS within 15 days of the notice of the initial determination. Section 425.802(a)(2) provides that reconsiderations may be heard orally (that is, in person, by telephone or other electronic means) or on-the-record (review of submitted documentation) at the discretion of the reconsideration official.

b. Proposed Revisions

To date, all reconsideration review requests have been on-the-record reviews. As explained in the December 2014 proposed rule, we believe that on-the-record reviews are fair to both parties. We noted that our experience to

date demonstrated that a robust oral review was not necessary in light of the narrow scope of review. We found that the issues eligible for review could be easily communicated in a detailed writing by both parties and did not require in person witness testimony. We also noted that on-the-record reviews do not require as many agency resources and therefore would ensure that decisions are made in a timely manner.

Accordingly, we proposed to modify § 425.802 to permit only on-the-record reviews of reconsideration requests. Additionally, we proposed to similarly modify § 425.804 to clarify that the reconsideration process allows both an ACO and CMS to submit one brief each in support of its position by the deadline established by the CMS reconsideration official.

Comment: Overall, commenters supported the proposals to permit only on-the-record reviews of reconsideration requests. However, a commenter questioned why CMS would arbitrarily constrain the process to a single brief. Another commenter suggested that CMS provide a reconsideration or grievance process for beneficiaries similar to these processes under MA.

Response: We believe that the current reconsideration review process offers a sufficient mechanism for stakeholders to appeal CMS decisions related to the Shared Savings Program. As outlined in § 425.802, we give ACOs 15 days to request a reconsideration from the notice of the initial determination and a second opportunity to request a review of the reconsideration official's recommendation under § 425.806.

We clarify that our proposal for the ACO and CMS to file a single brief is related to CMS or the ACO's initial request for reconsideration. If either CMS or the ACO disagrees with the initial decision of the reconsideration official, CMS or the ACO may request an on-the-record review from an independent CMS official who was not involved in the initial determination or the reconsideration review process. Our experience to date demonstrated that a robust oral review is not necessary in light of the narrow scope of review, and for the reasons noted in the December 2014 proposed rule, we will modify § 425.802 to permit only on-the-record reviews of reconsideration requests.

Additionally, although we believe the current regulations support submission of only a single brief, we want to ensure that the reconsideration official has the information needed to make a determination. For this reason and in response to comment, we will modify our proposal. Specifically, we will finalize the proposal that the

reconsideration process allows both an ACO and CMS to submit one brief each but also include that submission of additional briefs or evidence is at the discretion of the reconsideration official.

Finally, beneficiaries maintain the ability to dispute charges or file an appeal for a claim under the FFS program. The Shared Savings Program does not change any FFS beneficiary choices or benefits.

Comment: Several commenters appeared to believe that CMS does not have a reconsideration review process, stating that the lack of one is a violation of due process and that CMS should provide ACOs with a reconsideration process to challenge determinations. Finally, a few commenters objected to the statutory requirement to preclude administrative and judicial review of certain determinations under the program.

Response: As discussed earlier, we have established appeals procedures for the Shared Savings Program at 42 CFR part 425, subpart I. To the extent the commenters are concerned about the absence of administrative review for certain determinations, we note that section 1899(g) of the Act expressly precludes administrative and judicial review of these determinations, and as a result, we do not have the authority to offer administrative review for these determinations.

FINAL ACTION: We are finalizing our proposal at § 425.802 to permit only on-the-record reviews of reconsideration requests. Additionally, we are finalizing our proposal at § 425.804(a)(3) that the reconsideration review process permits the ACO and CMS to submit one brief each in support of its position by the deadline established by the CMS reconsideration official. Also, based on comments and a desire to ensure that the reconsideration official has the information necessary to make a determination, we will include in § 425.804(a)(3) that submission of additional briefs or evidence is at the sole discretion of the reconsideration official.

5. Monitoring ACO Compliance With Quality Performance Standards

We proposed a technical revision to § 425.316(c) to clarify our administrative enforcement authority when ACOs fail to meet the quality reporting requirements. Specifically, we proposed to remove § 425.316(c)(3), which sets forth various required actions the ACO must perform if it fails to report one or more quality measures or fails to report completely and accurately on all measures in a domain. We also

proposed to remove § 425.316(c)(4), which sets forth the administrative action we may take against an ACO if it exhibits a pattern of inaccurate or incomplete reporting of quality measures or fails to make timely corrections following notice to resubmit. The actions identified in § 425.316(c)(3) and (4) include request for missing or corrected information, request for a written explanation for the noncompliance, and termination. All of these actions are already authorized under § 425.216 and § 425.218. Therefore, to reduce redundancy, prevent confusion, and to streamline our regulations, we proposed to modify § 425.316(c) to remove § 425.316(c)(3) and (c)(4).

In addition, we proposed a technical change to § 425.316(c)(5), which currently provides that an ACO "will not qualify to share in savings in any year it fails to report fully and completely on the quality performance measures." We proposed to redesignate this paragraph as § 425.316(c)(3) and replace "fully and completely" with "accurately, completely, and timely" to align with § 425.500(f) and to emphasize the importance of timely submission of measures.

Comment: A few commenters supported the proposals, noting they would provide consistency within the program. A commenter requested that CMS clearly articulate what standards would apply to determine whether an ACO failed to accurately, completely, and timely report the quality measures.

Response: We appreciate the commenters' support for the proposed revisions to our regulatory language regarding requirements for accurate, complete, and timely submission of quality measures. We have provided clear guidance on an ACO's obligation to accurately, completely and timely report quality measures. We publish the annual deadlines for submitting quality measures and remind ACOs of the deadlines frequently. Additionally, we provide helpdesk support and hold daily support calls during the first and last weeks of the 8-week quality reporting submission period, and we hold weekly support calls during the 6 weeks in between. The support calls give ACOs an opportunity to inquire about each measure to make sure they understand how to report accurately and completely. We publish the submission deadline in advance of the submission period, announce it on support calls, and remind ACOs in emails, list serve postings, and weekly newsletter articles.

To meet the quality performance standard in PY1, the ACO must report

quality measures “completely, accurately, and timely.” In PY2 and PY3, the ACO must continue to report quality measures “completely, accurately, and timely” and must also meet minimum attainment on at least one pay-for-performance measure in each domain. Meeting the quality performance standard qualifies an ACO to share in savings for the performance year. As articulated in section II.C.3. of this final rule, we evaluate an ACO’s participation agreement renewal request on whether the ACO met the quality performance standards during at least 1 of the first 2 years of the previous agreement period.

FINAL ACTION: We are finalizing our proposals without change. Specifically, we are removing redundant sections of the regulation text (§ 425.316(c)(3) and (c)(4)). We are also finalizing our proposal to redesignate § 425.316(c)(5) as § 425.316(c)(3), and to make changes to indicate the ACO must report “accurately, completely, and timely” to emphasize the importance of timely submission of measures and to conform to language elsewhere in the program rules.

III. Collection of Information Requirements

As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. Consequently, the information collection requirements contained in this final rule need not be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary in order to make payment and policy changes to the Medicare Shared Savings Program established under section 1899 of the Act. The Shared Savings Program promotes accountability for a patient population, fosters the coordination of items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

B. Overall Impact

We examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded

Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis, which to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

1. Effects on the Medicare Program

The Shared Savings Program is a voluntary program involving an innovative mix of financial incentives for quality of care and efficiency gains within FFS Medicare. As a result, the changes to the Shared Savings Program being adopted in this final rule could result in a range of possible outcomes. In the November 2011 final rule (76 FR 67904), we indicated that participation in Track 1 might enable ACOs to gain the experience necessary to take on risk in a subsequent agreement period under a two-sided arrangement, possibly

enhancing the opportunity for greater program savings in years beyond the first agreement period. Conversely, if in that first agreement period, ACOs come to reliably predict a bias between expenditure benchmarks and actual assigned beneficiary costs that ensures an outcome—whether favorable or unfavorable—the program would be at risk for increasingly selective participation from favored ACOs and any real program savings could be overwhelmed by outsized shared-savings payments (76 FR 67964). Furthermore, even ACOs that opt for a two-sided arrangement could eventually terminate their agreements if they anticipate that efforts to improve efficiency are overshadowed by their particular market circumstances. This scenario could also contribute to selective program participation by ACOs favored by the national flat-dollar growth target, or favored by other unforeseen biases affecting performance.

However, as we indicated in the November 2011 final rule (76 FR 67964), even with the optional liability for a portion of excess expenditures, which offers less incentive to reduce growth in costs than a model involving full capitation, the opportunity to share in FFS Medicare savings still represents an incentive for efficiency. The actual effects of shared savings (and potential liabilities in the form of shared losses) will have varying degrees of influence on hospitals, primary care physicians, specialty physicians, and other providers and suppliers. Moreover, while certain care improvements might be achieved relatively quickly (for example, prevention of hospital readmissions and emergency-room visits for certain populations with chronic conditions), some ACOs might need more than 3 years to achieve comprehensive efficiency gains. As of January 2015, over 400 organizations have chosen to participate in the Shared Savings Program. These organizations care for over 7 million assigned FFS beneficiaries living in 47 states, plus Puerto Rico and the District of Columbia. Half of all ACOs characterize themselves as networks of individual practices and the other half include hospitals or facilities. In the fall of 2014, we announced the final financial reconciliation and quality performance results for performance year 1 for ACOs with 2012 and 2013 agreement start dates. ACOs outperformed other FFS providers that reported data on 17 out of 22 GPRO quality measures. ACOs that reported quality in both 2012 and 2013 also improved on 30 out of 33 quality measures.

Of the 220 ACOs with 2012 and 2013 start dates, 58 ACOs generated shared savings during their first performance year. They held spending \$705 million below their targets and earned shared savings payments of more than \$315 million as their share of program savings. One ACO in Track 2 overspent its target by \$10 million and owed shared losses of \$4 million. Total net savings to Medicare is close to \$383 million, including repayment of shared losses by one Track 2 ACO. An additional 60 ACOs reduced growth in health costs compared to their benchmark, but did not qualify for shared savings, as they did not meet the minimum savings threshold.

While evaluation of the program's overall impact is ongoing, the performance year 1 final financial reconciliation and quality results are within the range originally projected for the program's first year. Also, at this point, we have seen no evidence of systematic bias in ACO participation or performance that would raise questions about the savings that have been achieved.

Earlier in this final rule, we discussed changes in policy that are intended to better encourage ACO participation in performance risk-based models by:

- Easing the transition from Track 1 to Track 2.
- Providing refinements to Track 2.
- Adopting a new performance risk-based model with greater reward—Track 3.

Currently, an ACO will be able to apply to participate in Track 1 for its initial agreement period during which the ACO could be eligible for shared savings payments in all 3 performance years of the agreement period without the risk of being responsible for repayment of any losses if actual expenditures exceed the benchmark. However, rather than requiring all Track 1 ACOs to transition to a performance risk-based model in their second agreement period, as is currently required, we are improving the transition from the shared-savings only model to a performance risk-based model for Track 1 ACOs that might require additional experience with the program before taking on performance-based risk. Specifically, in this final rule, we are specifying that Track 1 ACOs may elect to continue participation under Track 1 for a subsequent agreement period at the same sharing rate as under the first agreement period provided they meet the general criteria established for an ACO to renew its 3-year participation agreement.

Under Track 2, which provides an opportunity for an ACO to receive a higher percentage of shared savings for all years of the agreement period, but with potential liability for shared losses in each of the agreement years if annual expenditures exceed the benchmark, we are providing the opportunity for ACOs to have some choice in the level of risk. Specifically, in this final rule, we are finalizing a policy that will permit an ACO in a two-sided performance risk track to choose its MSR and MLR from a range of options, so long as they are symmetrical. We believe this modification will enable ACOs to choose a level of risk with which they are comfortable and encourage ACOs to move more quickly to performance-based risk.

We are also establishing an additional performance risk-based option (Track 3) that offers a higher maximum shared savings percentage (75 percent) and performance payment limit (20 percent) than is available under Track 2 (60 percent and 15 percent respectively), and a cap on the amount of losses for which an ACO is liable that is fixed at 15 percent of its updated benchmark in each year. Similar to ACOs in Track 2, ACOs in Track 3 will be able to choose from a menu of symmetrical MSR/MLR levels. Also, under this model, beneficiaries will be assigned prospectively so an ACO will know in advance those beneficiaries for which it will be responsible.

We are finalizing a policy for resetting ACO benchmarks for a subsequent agreement period under which we will weight each benchmark year equally (approximately 33.3 percent for each year). We will also take into account the financial performance of the ACO from the prior agreement period when resetting the benchmark. If an ACO generated net savings over the previous agreement period, we will make an adjustment to the new benchmark to account for those savings.

As detailed in Table 9, we estimated at baseline (that is, without the changes detailed in this final rule) a total aggregate median impact of \$540 million in net federal savings for calendar years (CYs) 2016 through 2018 from the continued operation of the Shared Savings Program for ACOs electing a second agreement period starting in January 2016. The 10th and 90th percentiles of the estimate distribution, for this same time period, yield a net savings of \$340 million and \$800 million, respectively. These estimated impacts represent the effect on federal transfers of payments to Medicare providers and suppliers. The median estimated federal savings are

higher than the estimate of the program effects over the preceding CYs 2012 through 2015 published in the previous final rule (estimated median net savings of \$470 million for such 4 year period). This increase in savings is due to multiple factors related to maturation of the program, including continued phase-in of assumed savings potentials, lowered effective sharing rates due in part to rebased benchmarks, and increased collection of shared losses due to mandatory enrollment in Track 2 in a second agreement period. However, absent changes to improve the viability of participation for ACOs considering a second agreement period, we estimate fewer than 15 percent of ACOs would opt for continued participation under downside risk in Track 2 as required under the current regulations. We note that this estimate was revised downward from 25 percent in the December 2014 proposed rule based on emerging program experience (for example, assumptions for renewals and first-time applicants were revised in light of additional data provided by the 2015 start date). The decrease in the baseline median net savings previously estimated at \$730 million in the proposed rule is directly related to the revision to this estimate. Furthermore, we estimated up to half of such re-enrolling ACOs would ultimately drop out of the program by 2018 to avoid future shared loss liability.

Alternatively, as detailed in Table 10, by including the changes detailed in this final rule, the total aggregate median impact would increase to \$780 million in net federal savings for CYs 2016 through 2018. The tenth and ninetieth percentiles of the estimate distribution, for the same time period, yield net savings of \$230 million and \$1,430 million, respectively. Such median estimated federal savings are \$240 million greater than the \$540 million median net savings estimated at baseline absent the finalized changes. A key driver of an anticipated increase in net savings is through improved ACO participation levels in a second agreement period. We estimate that at least 90 percent of eligible ACOs will renew their participation in the Shared Savings Program if presented with the new options, primarily under Track 1 and, to a lesser extent, under Track 3. This expansion in the number of ACOs willing to continue their participation in the program is estimated to result in additional improvements in care efficiency of a magnitude significantly greater than the reduced shared loss receipts estimated at baseline (median shared loss dollars reduced by \$20

million relative to baseline) and the added shared savings payments flowing from a higher sharing rate in Track 3 and continued one-sided sharing available in Track 1, with all three tracks operating under more favorable rebasing parameters including equal base year weighting and adding a portion of savings from the prior agreement period to the baseline (median shared savings payments increased by \$970 million relative to baseline). Because final rule estimates reflect revised participation assumptions including lower Track 2 participation at baseline (as noted previously), the difference in shared loss receipts from baseline is revised downward from the \$140 million estimated in the proposed rule.

With respect to costs incurred by ACOs, as discussed later in this section, for purposes of this analysis, we are retaining our assumption included in our November 2011 final rule (76 FR 67969) of an average of \$0.58 million for start-up investment costs but are revising our assumption for average ongoing annual operating costs for an ACO participating in the Shared Savings Program to \$0.86 million, down from the \$1.27 million assumed in our November 2011 final rule (76 FR 67969). This revision is related to the lower average number of beneficiaries currently observed to be assigned to existing Shared Savings Program ACOs compared to the larger organizations participating in the Physician Group Practice Demonstration upon which the original assumption was based. We also believe the changes we are making in this final rule to streamline the administrative requirements for the program will further assist in lowering administrative costs.

For our analysis, we are comparing the effects of the changes being adopted in this final rule for a cohort of ACOs that either continued their participation in the Shared Savings Program, beginning in 2016 or newly begin their participation in that same year. For purposes of our analysis, we assumed that roughly one-quarter of ACOs will incur aggregate start-up investment costs in 2016, ranging from \$12 million under the baseline scenario to \$58 million under the policies being adopted in this final rule. Aggregate-ongoing operating costs are estimated to range from \$43 million under the baseline scenario to \$258 million under the policies adopted in this final rule. Both start-up investment and ongoing operating cost ranges assume an anticipated average participation level of 50 (baseline scenario) to 300 (with all changes) new or currently participating ACOs that establish or renew participation agreements in 2016. For purposes of this analysis, we assumed that some portion of ACOs currently participating in the program will not renew their participation agreement for a subsequent agreement period. As a result, under our baseline scenario, we assumed 50 ACOs will either renew or begin an agreement period in 2016—far fewer than the nearly 100 new ACOs that have entered the program in each of the last 2 years. The 3-year aggregate ongoing operating cost estimate also reflects our assumption that, under the baseline scenario, there would be a greater propensity for ACOs that have completed the full term of their initial agreement period, and that would be required to participate under Track 2 in their second agreement period, to drop out of the program after receiving poor results from their final settlement for the

first performance year under Track 2 in the new agreement period. Therefore, as illustrated in Table 9 for the baseline scenario, for CYs 2016 through 2018, total median ACO shared savings payments of \$160 million offset by \$50 million in shared losses coupled with the aggregate average start-up investment and ongoing operating cost of \$129 million result in an estimated net private cost of \$19 million. Alternatively, as illustrated in Table 10 for the all changes scenario, for CYs 2016 through 2018 the total median ACO shared savings payments of \$1,130 million, offset by \$30 million in shared losses, coupled with the aggregate average start-up investment and ongoing operating costs of \$822 million, result in an estimated net private benefit of \$278 million. Under the changes we are adopting in this final rule, ACOs are no longer required to move to a two-sided performance-based risk model in their second agreement period. As a result of this change and the other changes we are making in this final rule, the per-ACO average shared loss liability is reduced by 90 percent compared to the baseline. Therefore, the changes will likely prevent a significant number of ACOs that are due to renew their participation agreements in 2016 from leaving the program prior to 2018.

By encouraging greater Shared Savings Program participation, the changes in this rule will also benefit beneficiaries through broader improvements in accountability and care coordination than would occur under current regulations. Accordingly, we have prepared a regulatory impact analysis (RIA) that to the best of our ability presents the costs and benefits of this final rule.

TABLE 9—BASELINE (ABSENT ALL CHANGES) ESTIMATED NET FEDERAL SAVINGS, COSTS AND BENEFITS, CYs 2016 THROUGH 2018

	CY 2016 (million)	CY 2017 (million)	CY 2018 (million)	CYs (2016-2018) (million)
Net Federal Savings:				
10th Percentile	\$180	\$130	\$20	\$340
Median	270	200	60	540
90th Percentile	380	290	120	800
ACO Shared Savings:				
10th Percentile	20	30	40	100
Median	30	50	70	160
90th Percentile	50	80	110	230
ACO Shared Losses:				
10th Percentile	10	10	0	30
Median	20	30	0	50
90th Percentile	30	40	10	80

TABLE 9—BASELINE (ABSENT ALL CHANGES) ESTIMATED NET FEDERAL SAVINGS, COSTS AND BENEFITS, CYs 2016 THROUGH 2018—Continued

	CY 2016 (million)	CY 2017 (million)	CY 2018 (million)	CYs (2016-2018) (million)
Costs	The estimated aggregate average start-up investment and 3-year operating costs is \$129 million. The total estimated start-up investment costs average \$12 million, with ongoing costs averaging \$43 million, for the anticipated mean baseline participation of 50 ACOs.			
Benefits	Improved healthcare delivery and quality of care and better communication to beneficiaries through patient-centered care.			

Note that the percentiles for each individual year do not necessarily sum to equal the corresponding percentiles estimated for the total 3-year impact, in the column labeled CYs 2016 through 2018, due to the annual and overall distributions being constructed independently.

TABLE 10—ESTIMATED NET FEDERAL SAVINGS, COSTS AND BENEFITS UNDER THIS FINAL RULE CYs 2016 THROUGH 2018

	CY 2016 (million)	CY 2017 (million)	CY 2018 (million)	CYs (2016-2018) (million)
Net Federal Savings:				
10th Percentile	\$80	\$100	\$30	\$230
Median	250	290	240	780
90th Percentile	440	510	480	1,430
ACO Shared Savings:				
10th Percentile	260	300	390	960
Median	300	360	470	1,130
90th Percentile	360	420	550	1,310
ACO Shared Losses:				
10th Percentile	0	10	0	10
Median	10	20	0	30
90th Percentile	20	30	10	50
Costs	The estimated aggregate average start-up investment and 3-year operating costs is \$822 million. The total estimated start-up investment costs average \$58 million, with ongoing costs averaging \$258 million, for the anticipated mean participation of 300 ACOs.			
Benefits	Improved healthcare delivery and quality of care and better communication to beneficiaries through patient-centered care.			

Note that the percentiles for each individual year do not necessarily sum to equal the corresponding percentiles estimated for the total 3-year impact in the column labeled CYs 2016 through 2018, due to the annual and overall distributions being constructed independently. Also, the cost estimates for this table reflect our assumptions for increased ACO participation as well as changes in the mix of new and continuing ACOs.

There remains uncertainty as to the number of ACOs that will continue to participate in the program, provider and supplier response to the financial incentives offered by the program in the medium and long run, and the ultimate effectiveness of the changes in care delivery that may result as ACOs work to improve the quality and efficiency of patient care. These uncertainties continue to complicate efforts to assess the financial impacts of the Shared Savings Program and result in a wide range of potential outcomes regarding the net impact of the changes in this final rule on Medicare expenditures.

To best reflect these uncertainties, we continue to utilize a stochastic model that incorporates assumed probability distributions for each of the key variables that will affect the overall financial impact of the Shared Savings

Program. Using a Monte Carlo simulation approach, the model randomly draws a set of specific values for each variable, reflecting the expected covariance among variables, and calculates the program's financial impact based on the specific set of assumptions. We repeated the process for a total of 10,000 random trials, tabulating the resulting individual cost or savings estimates to produce a distribution of potential outcomes that reflects the assumed probability distributions of the incorporated variables, as shown in Table 10. In this way, we can evaluate the full range of potential outcomes based on all combinations of the many factors that will affect the financial impact, and with an indication of the likelihood of these outcomes. It is important to note that these indications do not represent

formal statistical probabilities in the usual sense, since the underlying assumptions for each of the factors in the model are based on reasonable judgments, using independent expert opinion when available.

The median result from the distribution of simulated outcomes represents the "best estimate" of the financial effect of the changes to the Shared Savings Program. The full distribution illustrates the uncertainty surrounding the mean or median financial impact from the simulation.

The median estimate reflects the net effects of—

- Reduced actual Medicare expenditures due to more efficient care;
- Shared savings payments to ACOs; and
- Payments to CMS for shared losses when actual expenditures exceed the

benchmark. That median indicates that the policies finalized in this rule will result in a projected total of \$780 million in net savings over CYs 2016 through 2018, or \$240 million greater than the median projected total at baseline without the changes being adopted in this final rule.

This net federal savings estimate, detailed at the top of Table 10, can be summed with the projected ACO shared savings less projected ACO shared losses—both also detailed in Table 10—to show the median expected effect on Medicare claim expenditures before accounting for shared savings payments (that is, the reduction in actual Medicare expenditures due to more efficient care).

A net savings (cost) occurs when payments of earned and unearned shared savings (less shared losses collected) resulting from: (1) Reductions in spending; (2) care redesign; and (3) normal group claim fluctuation, in total are less than (greater than) assumed savings from reductions in expenditures.

As continued emerging data become available on the differences between actual expenditures and the target expenditures reflected in ACO benchmarks, it may be possible to evaluate the financial effects with greater certainty. The estimate distribution shown in Table 11 provides an objective and reasonable indication of the likely range of financial outcomes, given the chosen variables and their assumed distributions at this time in the program's operation.

a. Assumptions and Uncertainties

We continue to rely on input gathered as part of the analysis for the existing regulation from a wide range of external experts, including credentialed actuaries, consultants, and academic researchers, to identify the pertinent variables that could determine the efficacy of the program, and to identify the reasonable ranges for each variable. We also continue to monitor emerging evidence from current participation in this program, the Pioneer ACO Model, and related published evidence where available.

There are a number of factors that are not fully reflected in our current modeling that may refine our modeling in future rulemaking:

- Number of participating ACOs, including the sensitivity to burdens of participation and the generosity of the sharing arrangement.
- Size mix of participating ACOs.
- Type of ACO that would consider accepting risk.

- Participating ACOs' current level of integration and preparedness for improving the quality and efficiency of care delivery.

- Baseline per-capita costs for ACOs, relative to the national average.
- Number and profile of providers and suppliers available to participate in the Shared Savings Program as a result of Innovation Center model initiatives.
- Range of gross savings achieved by ACOs, and the time required for full phase-in.
- Local variation in expected claims cost growth relative to the national average.
- Quality reporting scores and resulting attained sharing (or loss) percentages.
- Potential "spillover" effects between the Shared Savings Program and other value-based incentive programs implemented by CMS and other payers.

We assumed that overall between 0.8 million Medicare beneficiaries (under baseline) and 4.7 million Medicare beneficiaries (with all changes) would annually be assigned to between 50 and 300 ACOs beginning a new agreement period in 2016. Given data on current participation, we anticipate the program will continue to garner comparable levels of participation from markets exhibiting baseline per-capita FFS expenditures above, at, or below the national average. In addition, we assumed the level of savings generated by an ACO to positively correlate to its achieved quality performance score and resulting sharing percentage.

For estimating the impact of the changes, we assume that most ACOs (approximately 9 out of 10, on average) will choose Track 1. This is because the ACOs will seek to simultaneously: (1) Avoid the potential for financial loss if expenditures experience a significant upward fluctuation or efficiency improvements are less effective than planned; and (2) continue to build organizational experience to achieve a per-capita cost target as determined under the program's benchmark methodology.

In contrast, we assume that a minority of ACOs—disproportionately represented from a more capable subset of the total program participation—will opt for Track 3 in their second agreement period. These ACOs will be enabled by experience accepting risk or achieving success or both in their first agreement period in this program, and motivated by the provision for prospective assignment of beneficiaries and the greater sharing percentage available under this new option. A particularly important cause for

uncertainty in our estimate is the high degree of variability observed for local per-capita cost growth rates relative to the national average "flat dollar" growth (used to update ACO benchmarks). Performance measured against the benchmark or expenditure target effectively serves as the chief measure of efficiency for participating ACOs. Factors such as lower-than-average baseline per-capita expenditure and variation in local growth rates relative to the national average can trigger shared savings payments even in the absence of any efficiency gains. Similarly, some ACOs could find that factors, such as prevailing per-capita expenditure growth in their service area that is higher than the national average, limit efficiency gains and reduce or prevent shared savings.

b. Detailed Stochastic Modeling Results

Table 11 shows the distribution of the estimated net financial impact for the 10,000 stochastically generated trials under the policies being adopted in this final rule. (The amounts shown are in millions, with negative net impacts representing Medicare savings). The net impact is defined as the total cost of shared savings less—(1) Any amount of savings generated by reductions in actual expenditures; and (2) any shared losses collected from ACOs that accepted risk and have actual expenditures exceeding their benchmark.

The median estimate of the Shared Savings Program financial impact for ACOs potentially entering a second agreement period in calendar years 2016 through 2018 is a net federal savings of \$780 million, which is \$240 million higher than our estimate for the same period assuming a baseline scenario, which excludes the changes adopted in this final rule. This amount represents the "best estimate" of the financial impact of the Shared Savings Program during the applicable period. However, it is important to note the relatively wide range of possible outcomes. While over 97 percent of the stochastic trials resulted in net program savings, the 10th and 90th percentiles of the estimated distribution show net savings of \$230 million to net savings of \$1,430 million, respectively. In the extreme maximum and minimum scenarios, the results were as large as \$2.7 billion in savings or nearly \$500 million in costs, respectively.

The stochastic model and resulting financial estimates were prepared by the CMS Office of the Actuary (OACT). The median result of \$780 million in savings is a reasonable "point estimate" of the impact of the Shared Savings Program

during the period between 2016 and 2018 and reflects the changes being adopted in this final rule. However, we emphasize the possibility of outcomes differing substantially from the median estimate, as illustrated by the estimate distribution. As we analyze additional data on ACO performance in the first

agreement period, we may likely improve the precision of future financial impact estimates.

To the extent that the Shared Savings Program will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums would also be correspondingly lower or higher. In addition, because MA

payment rates depend on the level of spending within traditional FFS Medicare, savings or costs arising from the Shared Savings Program would result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

TABLE 11—STOCHASTIC DISTRIBUTION FOR THE ESTIMATED NET SAVINGS (–) OR COSTS (+) FOR CHANGES ADOPTED IN THIS FINAL RULE, CYs 2016 THROUGH 2018 (\$ millions)

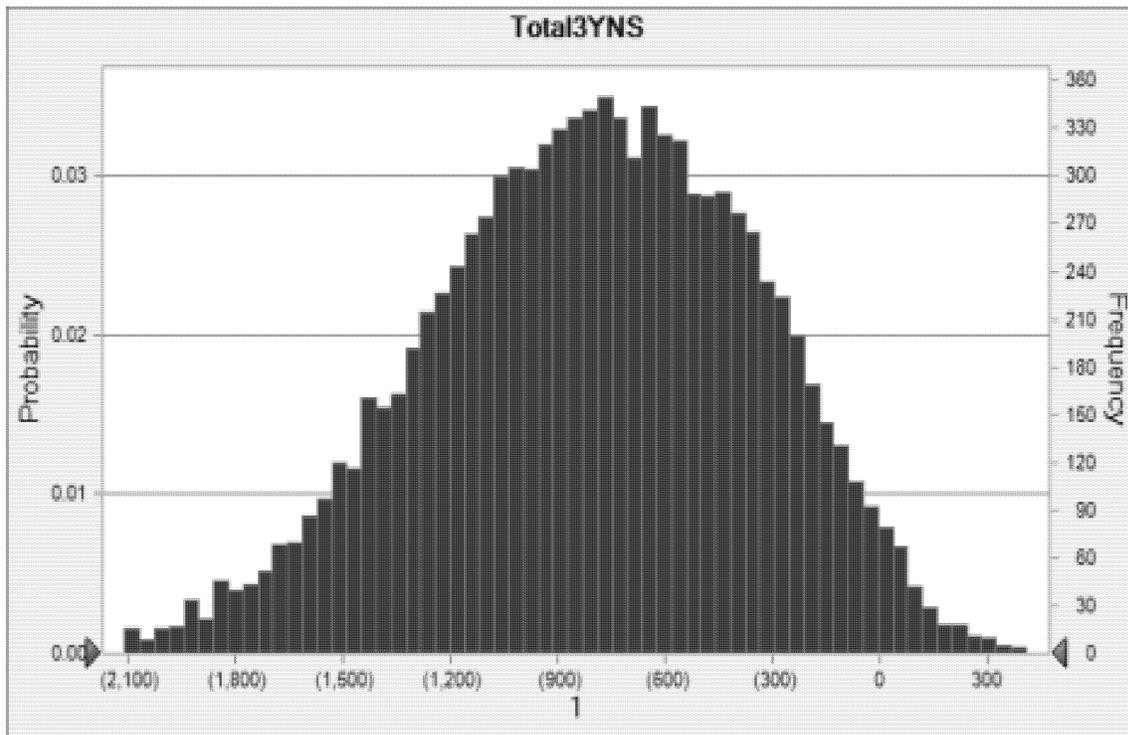
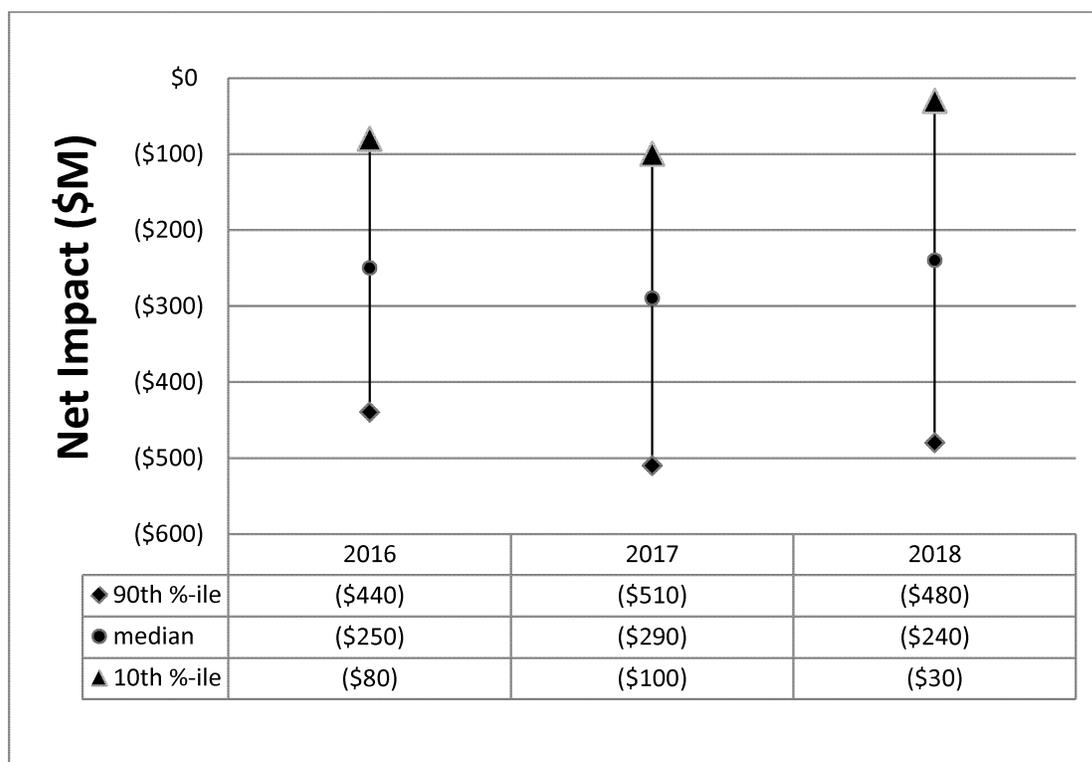


Table 12 shows the median estimated financial effects for the Shared Savings Program of ACOs entering in a new agreement period starting in 2016 and the associated 10th and 90th percentile ranges under the changes adopted in this final rule. Net savings (reflecting a net reduction in federal outlays) are expected to moderately contract over the 3-year period, from a median of

\$250 million in 2016 to \$240 million in 2018. This progression is related to the maturation of efficiencies achieved by renewing ACOs contrasted by progressive increases in shared savings payments due to increasing variability in expenditures in later performance years relative to a static benchmark expenditure baseline. To similar effect, the potential that Track 3 ACOs

experiencing losses may elect to voluntarily terminate their participation in the program could work to decrease net savings in the last year of the period relative to prior years. We note that the percentiles are tabulated for each year separately. Therefore, the overall net impact distribution (Table 10) will not necessarily exactly match the sum of distributions for each distinct year.

TABLE 12—STOCHASTIC DISTRIBUTION FOR ESTIMATED FEDERAL NET SAVINGS (–) OR COSTS (+) FOR CHANGES ADOPTED IN THIS FINAL RULE, CYs 2016 THROUGH 2018
(\$ millions)



c. Further Considerations

The impact analysis shown is only for the 3 years 2016 through 2018 corresponding to the second agreement period potentially available for the nearly 220 ACOs that will complete their first agreement period in 2015. Additional ACOs entered the program on January 1 of 2014 and 2015, totaling 123 and 89 new ACOs, respectively, and these ACOs would potentially be eligible to start a second agreement period beginning in 2017 or 2018. For all current participating groups of ACOs, uncertainties exist regarding their continued engagement with program goals and incentives, especially for ACOs who fail to generate shared savings revenue comparable to the cost of effective participation in the program. It is possible that, notwithstanding the enhancements adopted in this final rule, a significant drop-off in participation could materialize from ACOs failing to achieve significant revenue from shared savings in the short run. On the other hand, the Medicare Access and CHIP Reauthorization Act of 2015 may influence additional ACO formation in order for physicians to receive maximum updates under future

physician fee schedule updates. Independent of this recent legislation, value-based payment models are showing significant growth with arrangements being offered by state Medicaid programs, private insurers, and employer-sponsored plans. Moreover, we would also note that the number of providers and suppliers participating in these models and in the existing ACOs continues to grow. Therefore, providers may view continued participation in this program as part of a wider strategy for care redesign rather than be driven only by the potential for receiving incentives in the form of shared savings payments from the Medicare Shared Savings Program. Therefore, there remains a potential for broad gains in efficiency and quality of care delivery across all populations served by ACOs participating in the Shared Savings Program with possible additional “spillover” effects on federal savings potentially traceable to momentum originally created by this program. The stochastic model for estimating future program impacts starting in 2016 does not incorporate either of these divergent longer-run scenarios, but both remain

possibilities. An impact estimate expanded to include performance beyond the 2016 through 2018 agreement period would likely entail a significantly wider range of possible outcomes. However, additional emerging results of the first performance cycle will help inform estimates of the ongoing financial effects of the Shared Savings Program.

2. Effects on Beneficiaries

This program is still in the early stages of implementation. However, we continue to believe that the Shared Savings Program will benefit beneficiaries because the intent of the program is to—

- Encourage providers and suppliers to join together to form ACOs that will be accountable for the care provided to an assigned population of Medicare beneficiaries;
- Improve the coordination of FFS items and services; and
- Encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrates a dedication to, and focus on, patient-

centered care that results in higher quality care.

The benefits of a payment model that encourages providers and suppliers to become accountable for the overall care furnished to Medicare beneficiaries were evidenced by the PGP demonstration, upon which many features of the Shared Savings Program are based. Under the PGP demonstration, all of the PGP participants achieved improvements in their scores for most of the quality measures over time. While only 2 PGP participants met all 10 quality measure targets active in their 1st performance year, by the 5th performance year, 7 sites met all 32, or 100 percent of their targets, and the remaining 3 PGP participants met over 90 percent of the targets. More specifically, as we previously discussed in our November 2011 final rule (76 FR 67968), over the first 4 years of the PGP Demonstration, physician groups increased their quality scores an average of 10 percentage points on the 10 diabetes measures, 13 percentage points on the 10 congestive heart failure measures, 6 percentage points on the 7 coronary artery disease measures, 9 percentage points on the 2 cancer screening measures, and 3 percentage points on the 3 hypertension measures. Further analysis is provided in the Physician Group Practice Demonstration Evaluation Report (Report to Congress, 2009; http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_RTC_Sept.pdf).

As we have also discussed in November 2011 final rule (76 FR 67968), in addition to the overall increases in quality scores, we can examine the impact of the PGP Demonstration on quality by comparing the values of the seven claims-based quality measures for each PGP site and its comparison group. Our analysis found that, on the claims-based measures, PGP performance exceeded that of the comparison groups (CGs) on all measures between the base year (BY) and performance year 2 (PY2). It also found that the PGP sites exhibited more improvement than their CGs on all but one measure between the BY and PY2. Even after adjusting for pre-demonstration trends in the claims-based quality indicators, the PGP sites improved their claims-based quality process indicators more than their comparison groups.

Further, for the first year of the Pioneer ACO Model, all 32 Pioneer ACOs successfully reported quality measures and achieved the maximum quality score for complete and accurate reporting, earning incentive payments for their reporting accomplishments. Overall, Pioneer ACOs performed better

than published rates in FFS Medicare for all 15 clinical quality measures for which comparable data are available. In the second year of the Pioneer ACO Model, organizations increased the mean quality score by 19 percent and showed improvement on 28 of the 33 quality measures. Some of these measures included controlling high blood pressure, screening for future fall risk, screening for tobacco use and cessation, and patient experience in health promotion and education. The Pioneer ACOs improved the average performance score for patient and caregiver experience in 6 out of 7 measures.

The Independent Office of the Actuary in the Centers for Medicare & Medicaid Services (CMS) has certified that the Pioneer ACO Model, as tested in its first 2 performance years, meets the criteria for expansion to a larger population of Medicare beneficiaries.

Additionally, under the Shared Savings Program, almost all participating ACOs fully and completely reported quality measures for the 2013 reporting period, providing important information on current performance that can be used to improve patient engagement and make meaningful positive impacts on patient care.

In addition to the early quality data generated by participating organizations, we have anecdotal evidence that illustrates the importance of encouraging participation in the Shared Savings Program. For example, ACO providers/suppliers report very meaningful changes in patient engagement through beneficiary participation on the governing body of the ACO and on patient advisory committees. In response to beneficiary input, clinical practices are offering extended office hours, including weekend hours, and ensuring timely appointments and access to clinical staff. Using the data shared by CMS, ACOs are able to identify high risk beneficiaries that require additional clinical attention, assign case managers, and actively work to improve care for these beneficiaries. One ACO reported that it has implemented a process for performing in-home medication reconciliation and review of care plans as a follow up to hospital discharge and for one-third of those patients, discovered an intervention that avoided an unnecessary hospital readmission. Active identification and management of these patients has uncovered previously unaddressed issues that factored into patient inability to adhere to treatment plans. For example, an ACO reported that it has uncovered several psycho-social issues that were

resulting in avoidable readmissions such as the inability to self-medicate (the ACO arranged for home health services) and inadequate access to healthy food resources (the ACO worked with community stakeholders to have meals delivered to the patient's home).

Additionally, ACOs are using claims data to identify diagnoses prevalent in the assigned population and develop best practice guidelines for those conditions, and educating and alerting ACO participants and ACO providers/suppliers to standardize care processes and improve outcomes.

We expect that the changes in this final rule, specifically those easing administrative requirements, smoothing the transition to a performance risk-based model, and expanding opportunities to share in a higher level of savings will encourage greater program participation by ACOs, which will in turn increase the number of beneficiaries that can potentially benefit from high quality and more coordinated care. Nonetheless, this program does not affect beneficiaries' freedom of choice regarding which providers and suppliers they see for care since beneficiaries assigned to an ACO continue to be in the traditional Medicare program. Thus, beneficiaries may continue to choose providers and suppliers that do not participate in ACOs under the Shared Savings Program.

3. Effect on Providers and Suppliers

Based on discussions with ACOs that generated shared savings and demonstrated high quality care during their first performance year in the Shared Savings Program, we know that ACOs are busy implementing a variety of strategies designed to improve care coordination for beneficiaries and lower the rate of growth in expenditures. Most of these ACOs consider themselves to be "physician-based" organizations, rather than "hospital-based", although many state that a strong collaboration between inpatient and outpatient facilities is critical to better care coordination across sites of care. ACOs detailed several strategies that they believe were important such as careful pre-participation planning, transparency between the ACO leadership and its ACO participants and ACO providers/suppliers, education of ACO providers/suppliers regarding the ACO's care processes, strong physician leadership, and working to streamline and transform practices for highly efficient coordinated care across sites of care. Several clinicians in ACOs have reported to us that the ACO is providing them with the support and structure

needed to practice “how [they] always hoped [they] could.” All of these ACOs recognize that they are early in the process of implementing their strategies to improve care coordination and reduce the rate of growth in expenditures and have plans to refine and improve based upon their early lessons learned.

We realize that ACOs bear costs in building the organizational, financial and legal infrastructure that is necessary to participate in the Shared Savings Program and implementing the strategies previously articulated, as well as performing the tasks required of an ACO, such as: Quality reporting, conducting patient surveys, and investing in infrastructure for effective care coordination. While provider and supplier participation in the Shared Savings Program is voluntary, we have examined the potential costs of continued program participation.

In this final rule, we have revised several program policies in order to reduce the burden associated with the infrastructure, start-up and ongoing annual operating costs for participating ACOs in the Shared Savings Program. These revisions include simplifying the application and renewal process for certain ACOs with experience under either the Pioneer ACO Model or the Shared Savings Program, streamlining sharing of beneficiary data while continuing to give beneficiaries the opportunity to decline claims data sharing, and exempting changes to the public reporting template from marketing review. These significant policy modifications are discussed in detail in sections II.B., C., D, and G. of this final rule. Additionally, we continue to support streamlined processes, for example, under current program rules, eligible professionals who bill through the TIN of an ACO participant are treated as other PQRS Group Practice Reporting Option reporters and meet the PQRS requirements to avoid downward adjustments to their payments under the PFS when the ACO satisfactorily reports quality measures through the GPRO web interface. Because of this alignment with PQRS, burden is reduced for eligible professionals who are not required to report quality to CMS twice.

The Shared Savings Program is still relatively new, and the initial group of organizations that applied to participate has only recently completed the second performance year. Because of this limited experience with the program and flexibility regarding the composition of providers and suppliers within an ACO and the strategies that the provider community will pursue in

order to improve quality and reduce cost of care, precise estimates of expected provider costs or changes to their costs due to this final rule are difficult to create.

In our November 2011 final rule (76 FR 67968), we discussed a Government Accountability Office analysis of the PGP demonstration. The GAO study showed that both start-up and annual operating costs varied greatly across the participating practices. Thus, as we indicated in the November 2011 final rule (76 FR 67968), we use GAO’s analysis not to predict cost investment and operating expenditures, but to demonstrate that we expect the range of investment to vary greatly across ACOs and to provide the potential scope for aspiring participants.

For purposes of our current impact analysis, we are retaining the assumption included in our November 2011 final rule (76 FR 67969) of \$0.58 million in average start-up investment cost but are revising our assumption for average ongoing annual operating costs for an ACO from \$1.27 million to \$0.86 million to reflect the lower average number of beneficiaries assigned to existing Shared Savings Program ACOs (approximately 14,700 beneficiaries) compared to the 10 PGP sites examined by GAO (average size approximately 22,400 beneficiaries). Therefore, our cost estimates for purposes of this final rule reflect an average estimate of \$0.58 million for the start-up investment costs and \$0.86 million in ongoing annual operating costs for an ACO participating in the Shared Savings Program. Assuming an expected range of ACOs participating in the Shared Savings Program of 50 to 300 ACOs (baseline scenario and all changes scenario, respectively) yields an estimated aggregate start-up investment cost ranging from \$12 million to \$58 million (assuming at least 1 in 3 ACOs will incur start-up costs), with aggregate ongoing operating costs ranging from \$43 million to \$258 million for the agreement period coinciding with CYs 2016 through 2018. We are also assuming that ACOs participating in a track that includes two-sided performance-based risk will in certain cases drop out of the program after receiving poor results for the first performance period beginning in 2016. Such drop out activity is assumed to affect a greater proportion of ACOs at baseline than under the policies adopted in this because of the requirement that all renewing ACOs participate in Track 2 under the baseline scenario. When utilizing the anticipated mean participation rate of ACOs in the Shared Savings Program for such

agreement period coupled with the average start-up investment and ongoing annual operating costs for the up to 3 years that ACOs may participate for such agreement period, this yields estimated aggregate average start-up investment and ongoing operating costs of \$129 million for 50 ACOs (assuming no regulatory changes) to \$822 million for 300 ACOs (under the policies adopted in this final rule) for the agreement period covering CYs 2016 through 2018, although actual costs for individual ACOs are likely to vary and the total costs could be significantly lower or greater than the estimates previously provided.

While there will be a financial cost placed on ACOs that participate, there will be benefits to the respective organizations in the form of increased operational and healthcare delivery efficiency and potential to leverage enhanced organizational capabilities in value-based arrangements with other payers. Furthermore, as discussed previously, and explained in more detail in the preamble of this final rule, there will be an opportunity for financial reward for success in the program in the form of shared savings. As shown in Table 13, the estimate of the shared savings that will be paid to participating ACOs is a median of \$1,130 million during CYs 2016 through 2018, with \$960 million and \$1,310 million reflecting the 10th and 90th percentiles, respectively. (Similar to the previously presented stochastic distributions, the distribution represents uncertainty given the range of expert opinion, rather than a true statistical probability distribution.)

Compared to shared savings payments, under our changes to the program and revised assumptions, we anticipate collection from participating ACOs of a relatively moderate \$30 million in shared losses during the same period, with our 10th and 90th percentiles projecting \$10 million and \$50 million in shared losses collected, respectively. Shared losses decrease relative to the baseline (median of \$50 million over the same 3 years) because, in contrast to the baseline requirement, not all renewing ACOs will be required to enter Track 2 and take on downside risk. This estimate has been revised since publication of the proposed rule based on emerging information. Modeling indicates that not all ACOs choosing downside risk in a second agreement period, whether required, as under the current regulation or as an alternative option under the changes in this final rule, will achieve shared savings and some may incur a financial loss, due to the requirement to repay a

share of actual expenditures in excess of their benchmark as shared losses. The significantly reduced level of shared losses anticipated under this final rule is largely attributable to the option for eligible ACOs to be able to renew under Track 1, and illustrates a key reason why the program would be anticipated to see significantly stronger continued participation under the changes than at baseline.

Under the changes in this final rule, total median ACO shared savings payments (\$1,130 million) net of median shared losses (\$30 million) to ACOs with agreement periods covering CYs 2016 through 2018 are \$1,100 million in net payments. Such median total net payment amount, coupled with the aggregate average start-up investment and ongoing operating cost of \$822 million, incurred by the mean participation rate of ACOs in the Shared Savings Program during the same time period, yields a net private benefit of \$278 million. At baseline, absent the changes in this final rule, the median net payments to ACOs over the same time period would be only \$110 million (\$160 million in shared savings payments less \$50 million in shared losses). Such lower net sharing at baseline, combined with baseline average start-up investment and ongoing operating costs of \$129 million, yields a net private cost of \$19 million. We expect that a significant portion of Track 1 ACOs that are assumed to be unwilling to renew under the program

without the protection from downside risk will welcome the opportunity to continue under Track 1 for a second agreement period. Moreover, the changes reduce the estimated per-ACO average shared loss liability by 90 percent compared to the baseline, and increase the chance an ACO renewing in 2016 will continue to participate for all 3 years of the new agreement period.

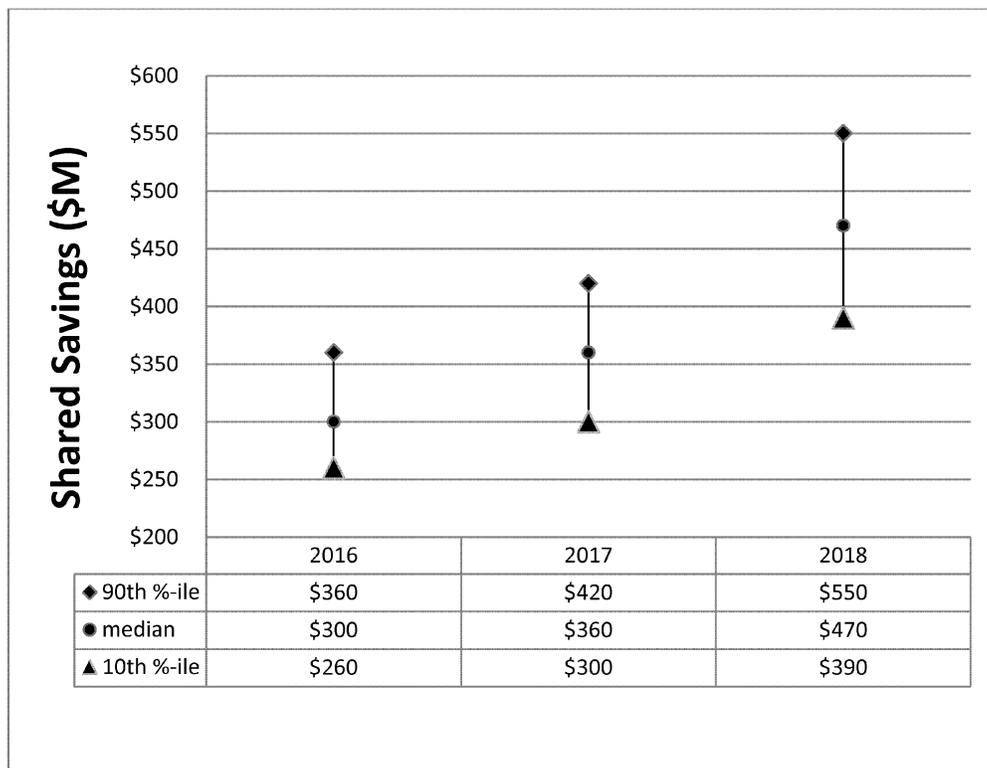
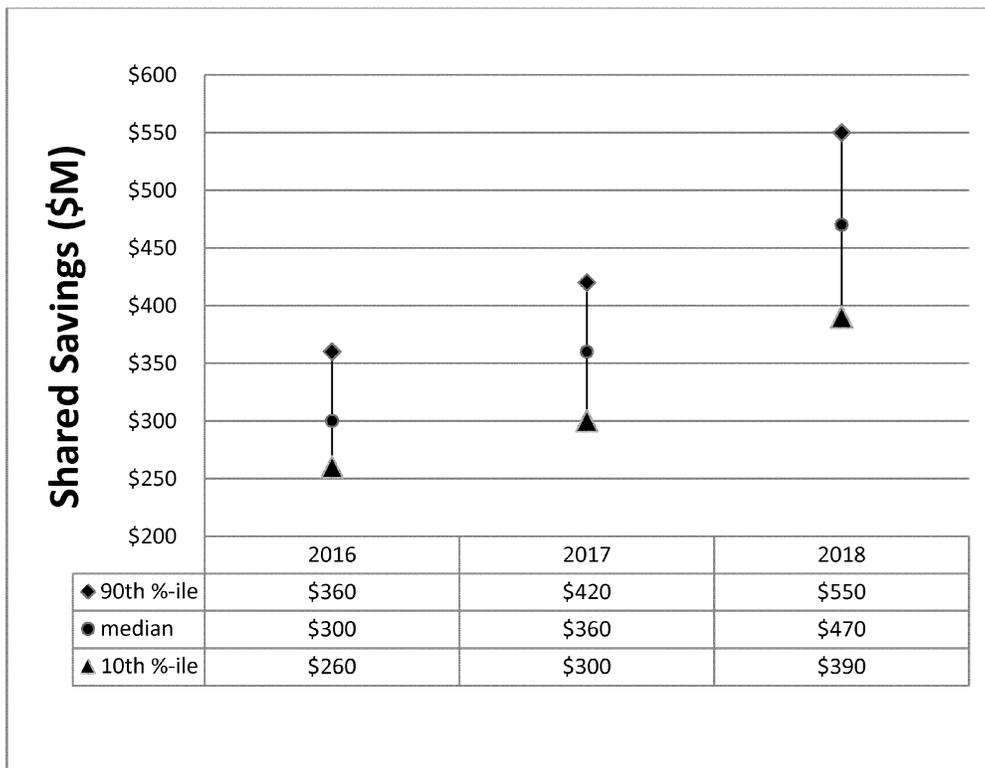
We noted that our estimates of net private benefits under the baseline and the changes being adopted in this final rule are influenced by assumptions that could vary in practice and thus result in a very different actual result than what was estimated. First, for purposes of our estimates of net private benefits under the baseline, we assumed that savings realized by existing ACOs during their first agreement period are built into their benchmarks and our baseline for their successive agreement period; however, changes to the rebasing methodology in this final rule, namely equal weighting of the base years and adding a portion of savings, will significantly reduce this effect especially for ACOs that generate significant savings in their first agreement period. However, most ACOs will likely still have to achieve greater efficiencies and quality improvements during their successive agreement period compared to their prior one in order to share in savings. Moreover, the extent to which these ACOs actually exceed or fall short of our assumed baseline savings will result in higher or

lower actual net private benefits relative to our estimate. Second, our estimates assumed a large proportion of existing Track 1 ACOs will continue participating under Track 1 for 2016 to 2018. All else being equal, the extent to which ACOs actually prefer to enroll in Track 3 with its higher maximum sharing rate and greater overall incentive for efficiency could increase the actual net private benefits created under the program. Finally, to the extent that actual ACO quality performance exceeds or falls short of our estimates, the net private benefits could be respectively higher or lower than what we estimated.

We also note that the net private benefits actually experienced by a given ACO may increase as a result of other benefits associated with participation in the Shared Savings Program. For example, an ACO that is participating in the Shared Savings Program and simultaneously receives value-based contracts from other payers may receive additional benefits. Such potential benefits are not considered in our analysis because they are not readily quantifiable. Therefore, we limit our benefit-cost estimate to shared savings and shared loss dollars received under the Shared Savings Program relative to estimated operational costs associated with participating in the program as previously described.

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TABLE 13—STOCHASTIC DISTRIBUTION FOR ESTIMATED ACO SHARED SAVINGS PAYMENTS, CYs 2016 THROUGH 2018
(\$ millions)



in the Shared Savings Program from \$1.27 million to \$0.86 million, stating they believe it underestimates the growing expenses that will accompany participation in the program.

Response: Our estimate reflects the average annual operating costs for the entire Shared Savings Program population of ACOs based on characteristics of ACOs that participated in 2012 and 2013. Thus, while particular ACOs may have higher (or lower) expenses as a result of their own baseline capabilities, we continue to believe that our estimate appropriately reflects the costs for the full range of ACOs participating in the program.

4. Effect 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. Most physician practices, hospitals, and other providers are small entities, either by virtue of their nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than \$7.5 to \$38.5 million in any 1 year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at <http://www.sba.gov/content/small-business-size-standards>. For purposes of the RFA, approximately 95 percent of physicians are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the Physician Fee Schedule (PFS).

Although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a FFS basis, we acknowledge that the program can affect many small entities and have made changes to our rules and regulations accordingly in order to minimize costs and administrative burden on such entities as well as to maximize their opportunity to participate. Small entities are both allowed and encouraged to participate in the Shared Savings Program, provided they have a minimum of 5,000 assigned beneficiaries, thereby potentially realizing the economic benefits of receiving shared savings resulting from the utilization of enhanced and efficient systems of care and care coordination. Therefore, a solo, small physician practice or other small entity may

realize economic benefits as a function of participating in this program and the utilization of enhanced clinical systems integration, which otherwise may not have been possible.

We have determined that this final rule will have a significant impact on a substantial number of small entities and we present more detailed analysis of these impacts, including costs and benefits to small entities and alternative policy considerations throughout this RIA. However, as detailed in this RIA, total median shared savings payments net of shared losses will offset about 134 percent of the average costs borne by entities participating in the Shared Savings Program, with an offset significantly greater than the cost of participation for the subset of ACOs that achieve shared savings in a given year, and no downside risk of significant shared losses for ACOs choosing to remain under Track 1 for a second agreement period. As a result, this regulatory impact section, together with the remainder of the preamble, constitutes our Regulatory Flexibility Analysis.

5. Effect on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Although the Shared Savings Program is a voluntary program, this final rule will have a significant impact on the operations of a substantial number of small rural hospitals. We have made changes to our regulations such that rural hospitals will have stronger incentives to participate in the program through offering a smoother transition to performance risk-based models, additional opportunities to potentially share in savings under new Track 3, and streamlined administrative requirements. In addition, the ACO Investment Model being implemented by the Center for Medicare and Medicaid Innovation features pre-paid shared savings in both upfront and ongoing per beneficiary per month payments for certain new ACOs entering the program in 2016 (and also for ACOs that entered the program in 2012 through 2015), with a priority for selecting ACOs in rural areas and areas with few ACOs. As detailed in this RIA, the estimated aggregate median impact of shared savings payments to

participating ACOs is approximately 134 percent of the average costs borne by entities that voluntarily participate in the Shared Savings Program, with an offset significantly greater than the cost of participation for the subset of ACOs that achieve shared savings in a given year, and no downside risk of significant shared loss penalties for ACOs choosing to remain under Track 1 for a second agreement period.

6. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately \$144 million. This final rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of \$144 million in any 1 year. Further, participation in this program is voluntary and is not mandated.

D. Alternatives Considered

In the November 2011 final rule (76 FR 67971), we noted in the regulatory impact analysis that many tenets of the program are statutorily mandated and thus allow for little, if any, flexibility in the rulemaking process. However, in some areas, the statute does provide flexibility, and we made our policy decisions regarding alternatives by balancing the effects of alternatives on a range of program stakeholders, including both providers and beneficiaries, the effects on the Medicare Trust Funds, and operational constraints. This final rule contains a range of modifications to program policies that take this balance into consideration. The preceding preamble provides descriptions of the various statutory provisions that are addressed in this final rule, identifies those policies where discretion is allowed and has been exercised, presents the rationales for our final policies and, where relevant, alternatives that were considered.

In addition to estimating the difference between impacts at baseline and under the policies adopted in this final rule, the stochastic model was also adapted to isolate marginal impacts for several alternative scenarios related to additional options for which the proposed rule sought comment. In one scenario, we researched the relationship between existing ACO base year per capita costs and our calculation of the corresponding county weighted average

FFS risk-adjusted per capita cost regional benchmarks. We observed significant variation in the relationship between individual ACO costs exhibited at baseline relative to their simulated regional benchmarks, with the standard error of percentage difference in costs approaching as high as 10 percent for samples of existing smaller-sized Shared Savings Program ACOs. Such variation not only would reduce the accuracy of savings measurements under a model using regional instead of ACO-historical benchmarks, it would also likely allow a significant number of ACOs to benefit from arbitrage in selecting the higher sharing in Track 3 with foreknowledge that large savings would likely be measured regardless of any real effort to increase efficiency. Certain other ACOs would be likely to drop out of the program rather than face a large gap between their actual baseline costs and their much lower regional benchmark. We estimated that such selective participation could reduce the gross savings generated, given fewer ACOs remaining in the model, yet increase overall payments due to remaining ACOs receiving higher benchmarks and selectively participating in Track 3 at artificially-low level of risk for generating shared losses. The net federal impact of the program under this scenario was estimated to reach as high as a \$1 billion dollar cost over the 2016 through 2018 agreement period.

However, we did note that information regarding regional benchmarks could potentially be utilized to adjust ACO benchmark calculations. For example, adding a portion of savings from the first agreement period into the second agreement period baseline (as finalized in this rule) could be targeted such that the resulting boost to an ACO's benchmark would not result in an adjusted benchmark greater than the ACO's regional benchmark. Such alternative policy could potentially be considered as part of future rulemaking to provide targeted benchmark rebasing relief to ACOs that demonstrate efficiency improvement in the form of savings in the first agreement period as well as efficiency attainment in the form of lower absolute cost than their region.

Another potential use of information regarding regional spending could involve utilization of the change in regional spending over time specific to each ACO to adjust an ACO's historical benchmark as part of rebasing. Therefore, we also considered the option discussed in the proposed rule for calculating a scaling factor that would adjust for the difference in the ACO's cost from benchmark year 3 (of

the ACO's first agreement period) to its regional benchmark for that same year. Under this option, the scaling factor would then be applied to the ACO's regional benchmark calculated for benchmark year 3 of the second agreement period. By adjusting for the relationship between the ACO and its region during the third benchmark year of the first agreement period, such methodology would be roughly equivalent to inflating the ACO's historical benchmark from the first agreement period to base year 3 of the second agreement period by applying the trend observed for the ACO's regional benchmark over that same time period. Modeling on historical data including regional trends at both county and Hospital Referral Region (HRR) levels indicated that the resulting trended and updated benchmarks would exhibit increased variation that would tend to boost second agreement period benchmarks for ACOs showing significant savings in the first agreement period to a significantly greater extent than will occur as a result of adding a portion of first agreement period savings to the new baseline (as stipulated in this rule), thereby increasing the cost of shared savings payments to these ACOs that will already have benefited to a lesser extent from the new rebasing policies included in this rule. Conversely, this alternative would also tend to significantly lower benchmarks for ACOs showing significant losses in the first agreement period. We estimated such policy would only modestly decrease shared savings payments to ACOs that would have already faced lower benchmarks under the equal weighting of the base years as otherwise stipulated in this rule, and that such modest savings from reduced shared savings payments would only fractionally offset significant increases in shared savings payments to favored ACOs. In other words, such ACOs would already be at a reduced likelihood for earning future shared savings; therefore, further lowering their benchmarks would produce diminishing effect on the reduction of shared savings payments. The estimated net result would be lower net program savings (\$540 million over 3 years) than we estimated under the changes in this final rule (\$780 million). We also estimated that such alternative benchmark—if weighted by 70 percent and blended with a 30 percent weight for the benchmark calculated as stipulated in this final rule (except assuming no portion of savings would be added back into the second agreement period base years)—would

mainly scale back the increase in benchmarks for favored ACOs enough to produce roughly the same net savings as this final rule methodology was estimated to produce (\$780 million over 2016 to 2018). We note that such estimates of the impact of regional trend on benchmark rebasing assume that ACO assigned beneficiary populations would not be excluded from the calculation of each individual ACO's regional benchmark trend, and that risk adjustment would be accomplished without bias from changes in the completeness and intensity of diagnosis coding for ACO beneficiaries. On the other hand, we also assumed that placing a lower weight on ACO's historical costs in setting future benchmarks, which makes achieving savings more financially attractive, would not increase the amount of gross savings that ACOs elect to achieve. A higher or lower weighting on the alternative benchmark could be required to produce a similar net impact as this final rule if these assumptions were changed.

The existing Shared Savings Program benchmarking methodology's reliance on rebasing has received attention in a number of recent analyses by academic researchers.² In theory, options that partially or fully de-link ACOs future benchmarks from current spending decisions increase the incentive to provide efficient care and, therefore, are likely to lead ACOs to achieve greater gross savings. While we believe the policies in this final rule provide a meaningful incentive for all ACOs to continue to participate and generate efficiency in care delivery in a second agreement period (for ACOs generating savings in the first agreement period there will be an explicit meaningful increase in their second agreement benchmark relative to their actual experience, and for ACOs showing losses, rebasing will provide a benchmark more in line with their emerging costs at the end of their first agreement period), we also believe that a long-term policy potentially featuring a blend of regional benchmark trend alongside rebasing could optimize the incentive for ACOs to invest in sustainable efficiency improvements in care delivery. The long-term effects of switching to a benchmarking methodology based on the blended

² Douven, Rudy; Thomas G. McGuire; and J. Michael McWilliams. (2015). "Avoiding Unintended Incentives in ACO Payment Models." *Health Affairs* (34)(1), 143–149; McWilliams, Michael J., Michael E. Chernew, Bruce E. Landon, and Aaron L. Schwartz. (2015) "Performance Differences in Year 1 of Pioneer Accountable Care Organizations." *New England Journal of Medicine*.

approach described previously will differ from the short-term effects in a number of ways.

For example, while as noted earlier the methodology being adopted in this final rule likely produces higher average benchmarks for the first agreement period following rebasing, the average level of benchmarks under this blended methodology would likely eventually rise relative to the average level of benchmarks under the methodology being adopted in this final rule since the savings ACOs achieve would no longer be fully reflected in ACOs' benchmarks in the long run (by contrast under the methodology being adopted in this final rule only a portion of savings is added to the baseline). Higher benchmarks would encourage greater participation in the program, increasing overall efficiency gains in FFS costs of care, although these gains would be at least partially offset by increased shared savings payments to ACOs that would have participated in the program even without a higher benchmark. Additionally, the program will likely begin to experience increased selective participation.

ACOs perceiving that losses measured in the first agreement period would be likely to continue to be reflected in future benchmarks to such an extent that they would not anticipate a legitimate opportunity to share in real savings they might generate in future years would be likely to drop out of the program. The decline in participation from such ACOs would grow over multiple agreement periods as the number of years grows between when the initial regional benchmark and scaling factor adjustment are calculated and the third base year of a future potential agreement period, leading to decreased program participation and lower overall efficiency gains in FFS

cost of care even as shared savings payments to ACOs benefiting from favorable variation in regional trend relative to actual ACO baseline cost would likely grow.

The cause of growing variation in cost over multiple years is related to many complex factors. One important factor is that the mix of patients assigned to an ACO will change over time, for example as other ACOs form and compete for patient assignment to a greater extent in future performance years than in the ACO's original baseline period. Variation is also created by changes in the providers that actually bill services under a given ACO participant TIN, or as the ACO makes wholesale changes to the list of ACO participant TINs associated with it. To illustrate this last factor, we note that nearly three-quarters of ACOs participating as of 2014 changed their list of ACO participant TINs for 2015, resulting in baseline assigned population per capita cost changes exceeding ± 20 percent for certain ACOs. As large numbers of ACOs have modified their ACO participants lists each year, and because assignment even to an ACO with a static ACO participant TIN makeup will often exhibit significant changes in the baseline cost of beneficiaries assigned over successive years (notwithstanding the effects of risk adjustment), the most recent historical data for an ACO remains the most accurate predictor of the ACO's expected future costs. We note that these differences in beneficiary assignment would be mitigated, but not eliminated by the approaches to adjusting for changes in patient mix and ACO participant TIN composition described in the preamble. Another important factor is that regions are not entirely homogenous, and the underlying trends in market conditions

may differ among ACOs located in different portions of a given region. Therefore developing future benchmarks from a fixed ACO baseline increases the error in measuring real savings or losses and leads to increasing net federal costs resulting from selective participation, with such costs likely to grow as the gap widens between the static baseline and the future agreement period within which a benchmark is calculated.

The importance of the improved incentives under the blended methodology may grow over time and work to offset the effects of increased selective participation, for at least two reasons. As ACOs gain experience with the payment model, they are likely to increasingly recognize the aspects in which the current benchmarking methodology penalizes the decision to achieve efficiencies and reduce efforts to achieve those efficiencies accordingly. In addition, we expect that the degree of gross savings that is feasible for ACOs to achieve will grow over time as ACOs gain experience with the payment model, making the extent to which the benchmarking methodology encourages ACOs to achieve savings increasingly important over time.

E. Accounting Statement and Table

As required by OMB Circular A-4 under Executive Order 12866, in Table 14, we have prepared an accounting statement showing the change in (A) net federal monetary transfers, (B) shared savings payments to ACOs net of shared loss payments from ACOs and (C) the aggregate cost of ACO operations for ACO participants and ACO providers/suppliers from 2016 to 2018 that are associated with the provisions of this final rule as compared to baseline.

TABLE 14—ACCOUNTING STATEMENT ESTIMATED IMPACTS
[CYs 2016–2018]

Category	Primary estimate (million)	Minimum estimate (million)	Maximum estimate (million)	Source citation (RIA, preamble, etc.)
Benefits				
Annualized monetized: Discount rate: 7%	–\$63.6	\$35.6	–\$168.1	Change from baseline (Table 9) to finalized changes (Table 10).
Annualized monetized: Discount rate: 3%	–70.9	37.2	–184.7	
Notes:	Negative values reflect reduction in federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.			

TABLE 14—ACCOUNTING STATEMENT ESTIMATED IMPACTS—Continued
[CYs 2016–2018]

Category	Primary estimate (million)	Minimum estimate (million)	Maximum estimate (million)	Source citation (RIA, preamble, etc.)
Benefits				
Annualized monetized: Discount rate: 7%	271.2	236.1	301.4	Change from baseline (Table 9) to finalized changes (Table 10).
Annualized monetized: Discount rate: 3%	293.9	255.7	326.4	
Notes:	Positive values reflect increase in aggregate shared savings net of shared losses. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as benefits/cost savings, rather than as transfers.			
Operational Cost				
Annualized monetized: Discount rate: 7%	191.0	Change from baseline (Table 9) to finalized changes (Table 10).
Annualized monetized: Discount rate: 3%	205.5	
Notes:	Positive values reflect increase in aggregate ACO operating costs largely attributable to assumed increased participation as a result of the policies included in this final rule compared to baseline.			

F. Conclusion

The analysis in this section, together with the remainder of this preamble, provides a Regulatory Impact Analysis. As a result of this final rule, the median estimate of the financial impact of the Shared Savings Program for CYs 2016 through 2018 would be net federal savings (after shared savings payments) of \$780 million. Under this final rule, median savings would be about \$240 million higher than we estimated assuming no changes for this period. Although this is the “best estimate” of the financial impact of the Shared Savings Program during CYs 2016 through 2018, a relatively wide range of possible outcomes exists. While over 97 percent of the stochastic trials resulted in net program savings, the 10th and 90th percentiles of the estimated distribution show net savings of \$230 million to net savings of \$1,430 million, respectively. In the extreme maximum and minimum scenarios, the results were as large as \$2.7 billion in savings or \$500 million in costs.

In addition, at the anticipated mean participation rate of ACOs in the Shared Savings Program, participating ACOs may experience an estimated aggregate average start-up investment and ongoing operating cost of \$822 million for CYs 2016 through 2018. Lastly, we estimate an aggregate median impact of \$1,130 million in shared savings payments to participating ACOs in the Shared Savings Program for CYs 2016 through 2018. The 10th and 90th percentiles of the estimate distribution, for the same

time period, yield shared savings payments to ACOs of \$960 million and \$1,310 million, respectively. Therefore, the total median ACO shared savings payments of \$1,130 million during CYs 2016 through 2018, net of a median \$30 million shared losses, coupled with the aggregate average start-up investment and ongoing operating cost of \$822 million yields a net private benefit of \$278 million.

Overall, we assumed greater participation by ACOs under the policies contained in this final rule due to our changes to ease the transition from Track 1 to Track 2, increase rebased benchmarks to account for a portion of savings in the prior agreement period, and adopt an alternative performance risk-based model—Track 3 with greater flexibility. These changes resulted in total shared savings increasing significantly, while shared losses decreased. Moreover, as participation in the Shared Savings Program continues to expand, we anticipate there will be a broader focus on care coordination and quality improvement among providers and suppliers within the Medicare program that will lead to both increased efficiency in the provision of care and improved quality of the care that is provided to beneficiaries.

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

List of Subjects in 42 CFR Part 425

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

For the reasons set forth in the preamble of this final rule, the Centers for Medicare & Medicaid Services amends 42 CFR part 425 to read as follows:

PART 425—MEDICARE SHARED SAVINGS PROGRAM

- 1. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 425.10 [Amended]

- 2. Amend § 425.10 as follows:
 - A. In paragraph (a) by removing the phrase “under FFS Medicare” and adding in its place the phrase “under FFS Medicare, except as permitted under section 1899(f) of the Act”.
 - B. In paragraph (b)(6) by removing the phrase “two-sided model” and adding in its place the phrase “two-sided models”.
- 3. Amend § 425.20 by:
 - A. Revising the definition of “ACO participant”.
 - B. Adding the definition of “ACO participant agreement” in alphabetical order.
 - C. Revising the definitions of “ACO professional”, “ACO provider/supplier”, “Agreement period”, and “Assignment”.

■ D. Adding the definition of "Assignment window" in alphabetical order.

■ E. Revising the definitions of "Continuously assigned beneficiary", "Hospital", and "Newly assigned beneficiary".

■ F. Adding the definition of "Participation agreement" in alphabetical order.

■ G. In the definition of "Performance year" by removing the phrase "in the ACO's agreement" and adding in its place the phrase "in the participation agreement".

■ H. Revising the definitions of "Primary care physician" and "Primary care services".

The revisions and additions read as follows:

§ 425.20 Definitions.

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ACO participant means an entity identified by a Medicare-enrolled billing TIN through which one or more ACO providers/suppliers bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118.

ACO participant agreement means the written agreement (as required at § 425.116) between the ACO and ACO participant in which the ACO participant agrees to participate in, and comply with, the requirements of the Shared Savings Program.

ACO professional means an individual who is Medicare-enrolled and bills for items and services furnished to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations and who is either of the following:

(1) A physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action.

(2) A practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

ACO provider/supplier means an individual or entity that meets all of the following:

(1) Is a—

(i) Provider (as defined at § 400.202 of this chapter); or

(ii) Supplier (as defined at § 400.202 of this chapter).

(2) Is enrolled in Medicare.

(3) Bills for items and services furnished to Medicare fee-for-service beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations.

(4) Is included on the list of ACO providers/suppliers that is required under § 425.118.

Agreement period means the term of the participation agreement, which is 3 performance years unless otherwise specified in the participation agreement.

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Assignment means the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from ACO professionals so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care during a given benchmark or performance year.

Assignment window means the 12-month period used to assign beneficiaries to an ACO.

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Continuously assigned beneficiary means a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year.

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Hospital means a hospital as defined in section 1886(d)(1)(B) of the Act.

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Newly assigned beneficiary means a beneficiary that is assigned to the ACO in the current performance year who was neither assigned to nor received a primary care service from any of the ACO participants during the assignment window for the most recent prior benchmark or performance year.

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Participation agreement means the written agreement required under § 425.208(a) between the ACO and CMS that, along with the regulations in this part, govern the ACO's participation in the Shared Savings Program.

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Primary care physician means a physician included in an attestation by the ACO as provided under § 425.404 for services furnished in an FQHC or RHC, or a physician who has a primary care specialty designation of—

(1) For performance years 2012 through 2015, internal medicine, general practice, family practice, or geriatric medicine; and

(2) For performance year 2016 and subsequent years, internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine.

Primary care services means the set of services identified by the following HCPCS codes:

(1) For performance years 2012 through 2015 as follows:

(i) 99201 through 99215.

(ii)(A) 99304 through 99340 and 99341 through 99350.

(B) G0402 (the code for the Welcome to Medicare visit).

(C) G0438 and G0439 (codes for the annual wellness visits).

(iii) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(2) For performance years 2016 and subsequent years as follows:

(i) 99201 through 99215.

(ii)(A) 99304 through 99340 and 99341 through 99350.

(B) G0402 (the code for the Welcome to Medicare visit).

(C) G0438 and G0439 (codes for the annual wellness visits).

(iii) Revenue center codes 0521, 0522, 0524, and 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(iv) 99495, 99496, and 99490.

(3) Additional codes designated by CMS as primary care services for purposes of the Shared Savings Program, including new HCPCS/CPT and revenue center codes and any subsequently modified or replacement codes for the HCPCS/CPT and revenue center codes identified in paragraphs (1) through (2) of this definition.

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§ 425.100 [Amended]

■ 4. Amend § 425.100 as follows:

■ A. In paragraph (b) by removing the reference "under § 425.604 or § 425.606" and adding in its place the reference "under § 425.604, § 425.606 or § 425.610".

■ B. In paragraph (c) by removing the phrase "under the two-sided model" and adding in its place the phrase "under a two-sided model".

■ C. In paragraph (c) by removing the reference "under § 425.606" and adding in its place the reference "under § 425.606 or § 425.610".

■ 5. Amend § 425.104 as follows:

■ A. In paragraph (b), by removing the phrase "otherwise independent ACO participants must" and adding in its place the phrase "ACO participants, each of which is identified by a unique TIN, must".

- B. By adding paragraph (c).
The addition reads as follows:

§ 425.104 Legal entity.

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(c) An ACO formed by a single ACO participant may use its existing legal entity and governing body, provided it satisfies the other requirements in §§ 425.104 and 425.106.

- 6. Amend § 425.106 as follows:

- A. By revising paragraphs (a), (b)(3), (c)(1), and (c)(2).
■ B. By removing paragraphs (b)(4) and (b)(5).

The revisions read as follows:

§ 425.106 Shared governance.

(a) *General rule.* (1) An ACO must maintain an identifiable governing body with ultimate authority to execute the functions of an ACO as defined under this part, including but not limited to, the processes defined under § 425.112 to promote evidence-based medicine and patient engagement, to report on quality and cost measures, and to coordinate care.

(2) The governing body of the ACO must satisfy all of the following criteria:

- (i) Be the same as the governing body of the legal entity that is the ACO.
(ii) Be separate and unique to the ACO and must not be the same as the governing body of any ACO participant, except as provided in § 425.104(c).
(iii) Satisfy all other requirements of this section.

(b) * * *
(3) The governing body members must have a fiduciary duty to the ACO, including the duty of loyalty, and must act consistent with that fiduciary duty.

(c) * * *
(1) The ACO must—
(i) Establish a mechanism for shared governance among the ACO participants or combinations of ACO participants (as identified in § 425.102(a)) that formed the ACO; and

(ii) Provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.

(2) The ACO governing body must include a Medicare beneficiary who—
(i) Is served by the ACO;
(ii) Is not an ACO provider/supplier;
(iii) Does not have a conflict of interest with the ACO; and
(iv) Does not have an immediate family member who has a conflict of interest with the ACO.

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- 7. Amend § 425.108 by revising paragraph (c) and removing paragraph (e) to read as follows:

§ 425.108 Leadership and management.

* * * * *

(c) Clinical management and oversight must be managed by a senior-level medical director. The medical director must be all of the following:

- (1) A board-certified physician.
(2) Licensed in a State in which the ACO operates.

(3) Physically present on a regular basis at any clinic, office or other location of the ACO, an ACO participant, or an ACO provider/supplier.

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- 8. Amend § 425.110 by revising paragraphs (a)(2) and (b) to read as follows:

§ 425.110 Number of ACO professionals and beneficiaries.

(a) * * *

(2) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries as specified in paragraph (a)(1) of this section if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years, as calculated using the assignment methodology set forth in subpart E of this part. In the case of the third benchmark year, CMS uses the most recent data available to estimate the number of assigned beneficiaries.

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO may be subject to the actions described in §§ 425.216 and 425.218.

(1) While under a CAP, the ACO remains eligible for shared savings and losses and the MSR and MLR (if applicable) is set at a level consistent with the number of assigned beneficiaries.

(2) If the ACO's assigned population is not at least 5,000 by the end of the performance year specified by CMS in its request for a CAP, CMS terminates the participation agreement and the ACO is not eligible to share in savings for that performance year.

- 9. Amend § 425.112 by adding paragraphs (b)(4)(ii)(C) and (D) to read as follows:

§ 425.112 Required processes and patient-centeredness criteria.

* * * * *

(b) * * *

(4) * * *

(ii) * * *

(C) Describe how the ACO will encourage and promote use of enabling technologies for improving care coordination for beneficiaries. Enabling technologies may include one or more of the following:

(1) Electronic health records and other health IT tools.

(2) Telehealth services, including remote patient monitoring.

(3) Electronic exchange of health information.

(4) Other electronic tools to engage beneficiaries in their care.

(D) Describe how the ACO intends to partner with long-term and post-acute care providers, both inside and outside the ACO, to improve care coordination for their assigned beneficiaries.

- 10. Add § 425.116 to subpart B to read as follows:

§ 425.116 Agreements with ACO participants and ACO providers/suppliers

(a) *ACO participant agreements.* For performance year 2017 and subsequent performance years, the ACO must have an ACO participant agreement with each ACO participant that complies with the following criteria:

(1) The only parties to the agreement are the ACO and the ACO participant.

(2) The agreement must be signed on behalf of the ACO and the ACO participant by individuals who are authorized to bind the ACO and the ACO participant, respectively.

(3) The agreement must expressly require the ACO participant to agree, and to ensure that each ACO provider/supplier billing through the TIN of the ACO participant agrees, to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).

(4) The agreement must set forth the ACO participant's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F of this part, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO participant and its ACO providers/suppliers to participate in other Medicare demonstration projects or programs that involve shared savings.

(5) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO participant to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.

(6) The agreement must require the ACO participant to update its enrollment information, including the addition and deletion of ACO professionals and ACO providers/

suppliers billing through the TIN of the ACO participant, on a timely basis in accordance with Medicare program requirements and to notify the ACO of any such changes within 30 days after the change.

(7) The agreement must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement, to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS.

(8) The agreement must be for a term of at least 1 performance year and must articulate potential consequences for early termination from the ACO.

(9) The agreement must require completion of a close-out process upon termination or expiration of the agreement that requires the ACO participant to furnish all data necessary to complete the annual assessment of the ACO's quality of care and addresses other relevant matters.

(b) *Agreements with ACO providers/suppliers.* ACOs have the option of contracting directly with its ACO providers/suppliers regarding items and services furnished to beneficiaries aligned to the ACO. For performance year 2017 and subsequent performance years, an ACO's agreement with an ACO provider/supplier regarding such items and services must satisfy the following criteria:

(1) The only parties to the agreement are the ACO and the ACO provider/supplier.

(2) The agreement must be signed by the ACO provider/supplier and by an individual who is authorized to bind the ACO.

(3) The agreement must expressly require the ACO provider/supplier to agree to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable laws and regulations (including, but not limited to, those specified at § 425.208(b)).

(4) The agreement must set forth the ACO provider's/supplier's rights and obligations in, and representation by, the ACO, including without limitation, the quality reporting requirements set forth in subpart F of this part, the beneficiary notification requirements set forth at § 425.312, and how participation in the Shared Savings Program affects the ability of the ACO provider/supplier to participate in other

Medicare demonstration projects or programs that involve shared savings.

(5) The agreement must describe how the opportunity to receive shared savings or other financial arrangements will encourage the ACO provider/supplier to adhere to the quality assurance and improvement program and evidence-based medicine guidelines established by the ACO.

(6) The agreement must require the ACO provider/supplier to—

(i) Update its enrollment information on a timely basis in accordance with Medicare program requirements; and

(ii) Notify the ACO of any such changes within 30 days after the change.

(7) The agreement must permit the ACO to take remedial action including the following against the ACO provider/supplier to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues, including those identified by CMS:

(i) Imposition of a corrective action plan.

(ii) Denial of incentive payments.

(iii) Termination of the ACO participant agreement.

(c) *Submission of agreements.* The ACO must submit an executed ACO participant agreement for each ACO participant at the time of its initial application, participation agreement renewal process, and when adding to its list of ACO participants in accordance with § 425.118. The agreements may be submitted in the form and manner set forth in § 425.204(c)(6) or as otherwise specified by CMS.

■ 11. Add § 425.118 to subpart B to read as follows:

§ 425.118 Required reporting of ACO participants and ACO providers/suppliers.

(a) *List requirements.* (1) The ACO must maintain, update, and submit to CMS an accurate and complete list identifying each ACO participant (including its Medicare-enrolled TIN) and each ACO provider/supplier (including its NPI or other identifier) in accordance with this section.

(2) Before the start of an agreement period, before each performance year thereafter, and at such other times as specified by CMS, the ACO must submit to CMS an ACO participant list and an ACO provider/supplier list. The ACO may request consideration of claims billed under merged and acquired Medicare-enrolled TINs in accordance with the process set forth at § 425.204(g).

(3) The ACO must certify the submitted lists in accordance with § 425.302(a)(2).

(4) All Medicare enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of the ACO participant must be included on the ACO provider/supplier list and must agree to participate in the ACO and comply with the requirements of the Shared Savings Program before the ACO submits the ACO participant list and the ACO provider/supplier list.

(b) *Changes to the ACO participant list—(1) Additions.* (i) An ACO must submit to CMS a request to add an entity and its Medicare enrolled TIN to its ACO participant list. This request must be submitted at such time and in the form and manner specified by CMS.

(ii) If CMS approves the request, the entity and its Medicare enrolled TIN is added to the ACO participant list effective January 1 of the following performance year.

(iii) CMS may deny the request on the basis that the entity is not eligible to be an ACO participant or on the basis of the results of the screening performed under § 425.304(b).

(2) *Deletions.* (i) An ACO must notify CMS no later than 30 days after the termination of an ACO participant agreement. Such notice must be submitted in the form and manner specified by CMS and must include the termination date of the ACO participant agreement.

(ii) The entity is deleted from the ACO participant list as of the termination date of the ACO participant agreement.

(3) *Adjustments.* (i) CMS annually adjusts an ACO's assignment, historical benchmark, the quality reporting sample, and the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the list of ACO participants that is submitted to CMS before the start of a performance year in accordance with paragraph (a) of this section.

(ii) Absent unusual circumstances, CMS does not make adjustments during the performance year to the ACO's assignment, historical benchmark, performance year financial calculations, the quality reporting sample, or the obligation of the ACO to report on behalf of eligible professionals that bill under the TIN of an ACO participant for certain CMS quality initiatives to reflect the addition or deletion of entities from the ACO participant list that become effective during the performance year. CMS has sole discretion to determine whether unusual circumstances exist that would warrant such adjustments.

(c) *Changes to the ACO provider/supplier list*—(1) *Additions.* (i) An ACO must notify CMS within 30 days after an individual or entity becomes a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) If the ACO timely submits notice to CMS, the addition of an individual or entity to the ACO provider/supplier list is effective on the date specified in the notice furnished to CMS, but no earlier than 30 days before the date of the notice. If the ACO fails to submit timely notice to CMS, the addition of an individual or entity to the ACO provider/supplier list is effective on the date of the notice.

(2) *Deletions.* (i) An ACO must notify CMS no later than 30 days after an individual or entity ceases to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant. The notice must be submitted in the form and manner specified by CMS.

(ii) The deletion of an ACO provider/supplier from the ACO provider/supplier list is effective on the date the individual or entity ceased to be a Medicare-enrolled provider or supplier that bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a billing number assigned to the TIN of an ACO participant.

(d) *Update of Medicare enrollment information.* The ACO must ensure that all changes to enrollment information for ACO participants and ACO providers/suppliers, including changes to reassignment of the right to receive Medicare payment, are reported to CMS consistent with § 424.516. r

■ 12. Amend § 425.200 as follows:

■ A. By revising the section heading.
 ■ B. In paragraph (a), by removing the term “three” and adding in its place the figure “3”.

■ C. In paragraphs (b) introductory text (paragraph heading), (b)(1) introductory text, (b)(1)(i), (b)(1)(ii), (b)(2)(ii), and (c)(1) by removing the term “agreement” each time it appears and adding in its place the term “participation agreement”.

The revision reads as follows:

§ 425.200 Participation agreement with CMS.

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■ 13. Amend § 425.202 by revising paragraphs (b) and (c) to read as follows:

§ 425.202 Application procedures.

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(b) *Condensed application form.* (1) PGP demonstration sites applying to participate in the Shared Savings Program will have an opportunity to complete a condensed application form.

(2) A Pioneer ACO may use a condensed application form to apply for participation in the Shared Savings Program if it satisfies all of the following criteria:

(i) The applicant is the same legal entity as the Pioneer ACO.

(ii) The applicant’s ACO participant list does not contain any ACO participant TINs that did not appear on the “Confirmed Annual TIN/NPI List” (as defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO’s last full performance year in the Pioneer ACO Model.

(iii) The applicant is not applying to participate in the one-sided model.

(c) *Application review.* CMS reviews applications in accordance with § 425.206.

■ 14. Amend § 425.204 by:

■ A. In paragraph (b)(2) by removing the terms “ACO agreement” and adding in its place the terms “participation agreement”.

■ B. In paragraph (b)(3) by removing the term “agreement” and adding in its place the terms “participation agreement”.

■ C. Revising paragraphs (c)(1) introductory text and (c)(1)(i), (iii), and (iv).

■ D. In paragraph (c)(1)(vi) by removing the terms “ACO’s agreement” and adding in its place the terms “participation agreement”.

■ E. Revising paragraph (c)(3).

■ F. In paragraph (c)(4)(ii), by removing the phrase “among multiple, independent ACO participants” and adding in its place the phrase “among two or more ACO participants”.

■ G. Revising paragraph (c)(5)(i).

■ H. Adding paragraph (c)(6).

■ I. In paragraph (e)(1), removing the phrase “an ACO must specify whether it is applying to participate in Track 1 or Track 2” and adding in its place the phrase “an ACO must specify the Track for which it is applying”

■ J. Revising paragraph (f).

■ K. Adding paragraph (g).

The revisions and additions read as follows:

§ 425.204 Content of the application.

* * * * *

(c) * * *

(1) As part of its application, and upon request thereafter, an ACO must submit to CMS the following supporting materials to demonstrate that the ACO satisfies the requirements set forth in this part:

(i) Documents (for example, ACO participant agreements, agreements with ACO providers/suppliers, employment contracts, and operating policies) sufficient to describe the ACO participants’ and ACO providers’/suppliers’ rights and obligations in and representation by the ACO, and how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidence-based clinical guidelines.

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(iii) Materials documenting the ACO’s organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders specifically noted in § 425.108 and § 425.112(a)(2).

(iv) Evidence that the governing body—

- (A) Is an identifiable body;
- (B) Represents a mechanism for shared governance for ACO participants;
- (C) Is composed of representatives of its ACO participants; and
- (D) Is at least 75 percent controlled by its ACO participants.

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(3) If an ACO requests an exception to the governing body requirement in § 425.106(c)(2) or (c)(3), the ACO must describe—

(i) Why it seeks to differ from the requirement; and

(ii) If seeking an exception to (c)(2), how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

(iii) If seeking an exception to the requirement at (c)(3), why the ACO is unable to meet the requirement and how it will involve ACO participants in innovative ways in ACO governance.

* * * * *

(5) * * *

(i) The ACO must submit a list of all ACO participants and ACO providers/suppliers in accordance with § 425.118.

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(6) As part of the application process and upon request by CMS, the ACO must submit documents demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing

functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. The evidence to be submitted must include, without limitation, sample or form agreements and, in the case of ACO participant agreements, the first and signature page(s) of each executed ACO participant agreement. CMS may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. The ACO must certify that all of its ACO participant agreements comply with the requirements of this part.

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(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay all shared losses for which it may be liable under a two-sided model.

(i) As part of the application or participation agreement renewal process, an ACO that is seeking to participate under a two-sided model of the Shared Savings Program must submit for CMS approval documentation that it is capable of repaying shared losses that it may incur during the agreement period.

(ii) The documentation specified in paragraph (f)(1)(i) of this section must include details supporting the adequacy of the mechanism for repaying shared losses equal to at least 1 percent of the ACO's total per capita Medicare parts A and B fee-for-service expenditures for its assigned beneficiaries based on expenditures used to calculate the benchmark for the applicable agreement period, as estimated by CMS at the time of application or participation agreement renewal.

(2) An ACO may demonstrate its ability to repay shared losses by placing funds in escrow, obtaining a surety bond, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing a combination of such repayment mechanisms, that will ensure its ability to repay the Medicare program.

(3) An ACO participating under a two-sided model must demonstrate the adequacy of this repayment mechanism prior to the start of each agreement period in which it takes risk, and upon request thereafter. After the repayment mechanism has been used to repay any portion of shared losses owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days.

(4) The repayment mechanism must be in effect for a sufficient period of time after the conclusion of the agreement period to permit CMS to

calculate the amount of shared losses owed and to collect this amount from the ACO.

(g) *Consideration of claims billed under merged and acquired Medicare-enrolled TINs.* An ACO may request that CMS consider, for purposes of beneficiary assignment and establishing the ACO's benchmark under § 425.602, claims billed by Medicare-enrolled entities' TINs that have been acquired through sale or merger by an ACO participant.

(1) The ACO may include an acquired Medicare-enrolled entity's TIN on its ACO participant list under the following circumstances:

(i) The ACO participant has subsumed the acquired entity's TIN in its entirety, including all of the providers and suppliers that reassigned their right to receive Medicare payment to the acquired entity's Medicare-enrolled TIN.

(ii) Each provider or supplier that previously reassigned his or her right to receive Medicare payment to the acquired entity's TIN has reassigned his or her right to receive Medicare payment to the TIN of the acquiring ACO participant and has been added to the ACO provider/supplier list under paragraph (c)(5) of the section.

(iii) The acquired entity's TIN is no longer used to bill Medicare.

(2) The ACO must submit the following supporting documentation in the form and manner specified by CMS.

(i) An attestation that—
(A) Identifies by Medicare-enrolled TIN both the acquired entity and the ACO participant that acquired it;
(B) Specifies that all the providers and suppliers that previously reassigned their right to receive Medicare payment to the acquired entity's TIN have reassigned such right to the TIN of the identified ACO participant and have been added to the ACO provider/supplier list under paragraph (c)(5) of this section; and

(C) Specifies that the acquired entity's TIN is no longer used to bill Medicare.

(ii) Documentation sufficient to demonstrate that the acquired entity's TIN was merged with or purchased by the ACO participant.

■ 15. Amend § 425.206 by revising paragraph (a) to read as follows:

§ 425.206 Evaluation procedures for applications.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an ACO's application to determine whether an applicant satisfies the requirements of this part and is qualified to participate in the Shared Savings Program, and approves or denies

applications accordingly. Applications are approved or denied on the basis of the following:

(i) Information contained in and submitted with the application by an application deadline specified by CMS.

(ii) Supplemental information that was submitted in response to a CMS request and by a deadline specified by CMS.

(iii) Other information available to CMS.

(2) CMS notifies an ACO applicant when supplemental information is required for CMS to make a determination on the ACO's application and provides an opportunity for the ACO to submit the information.

(3) CMS may deny an application if an ACO applicant fails to submit requested information by the deadlines established by CMS.

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■ 16. Amend § 425.212 by revising the section heading and paragraph (a) to read as follows:

§ 425.212 Changes to program requirements during the agreement period.

(a) An ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute:

(1) Eligibility requirements concerning the structure and governance of ACOs.

(2) Calculation of sharing rate.

* * * * *

■ 17. Amend § 425.214 by:

■ A. Revising the section heading.

■ B. Removing paragraph (a).

■ C. Redesignating paragraphs (b) and (c) as paragraphs (a) and (b), respectively.

■ D. Revising newly redesignated paragraph (a).

■ E. In newly redesignated paragraph (b) introductory text, removing the phrase "Upon receiving" and adding in its place the phrase "Upon becoming aware of a significant change or receiving".

■ F. In newly redesignated paragraphs (b)(2) and (4) by removing the term "agreement" and adding in its place the terms "participation agreement".

The revisions read as follows:

§ 425.214 Managing changes to the ACO during the agreement period.

(a)(1) An ACO must notify CMS within 30 days of any significant change.

(2) An ACO's failure to notify CMS of a significant change does not preclude CMS from determining that the ACO has experienced a significant change.

(3) A “significant change” occurs when an ACO is no longer able to meet the eligibility or program requirements of this part.

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§ 425.216 [Amended]

■ 18. Amend § 425.216(b)(2) by removing the term “ACO’s agreement” and adding in its place the terms “participation agreement”.

■ 19. Amend § 425.218 by:

■ A. Revising the section heading.

■ B. Adding paragraphs (b)(4) and (5).

The revision and additions read as follows:

§ 425.218 Termination of the participation agreement by CMS.

* * * * *

(b) * * *

(4) Failure to comply with CMS requests for documentation or other information by the deadline specified by CMS.

(5) Submitting false or fraudulent data or information.

* * * * *

■ 20. Amend § 425.220 by revising the section heading and removing and reserving paragraph (b).

The revision reads as follows:

§ 425.220 Termination of the participation agreement by the ACO.

* * * * *

■ 21. Add § 425.221 to read as follows:

§ 425.221 Close-out procedures and payment consequences of early termination.

(a) *Close-out procedures.* (1) An ACO whose participation agreement has expired or is terminated by CMS under § 425.218 or by the ACO under § 425.220 must implement close-out procedures including but not limited to the following issues in a form and manner and by a deadline specified by CMS:

(i) Notice to ACO participants of termination.

(ii) Record retention.

(iii) Data sharing.

(iv) Quality reporting.

(v) Beneficiary continuity of care.

(2) ACOs that fail to complete close-out procedures in the form and manner and by the deadline specified by CMS will not be eligible to share in savings.

(b) *Payment consequences of early termination.* (1) An ACO whose participation agreement is terminated by the ACO under § 425.220 is eligible to receive shared savings for the performance year during which the termination becomes effective only if—

(i) CMS designates or approves an effective date of termination of

December 31st of such performance year;

(ii) The ACO has completed all close-out procedures by the deadline specified by CMS; and

(iii) The ACO has satisfied the criteria for sharing in savings for the performance year.

(2) An ACO that terminates its participation agreement under § 425.220 before December 31 of a performance year or whose participation agreement is terminated at any time by CMS under § 425.218 is not eligible to receive shared savings for the performance year during which the termination becomes effective.

■ 22. Amend § 425.222 by revising paragraph (c) to read as follows:

§ 425.222 Re-application after termination.

* * * * *

(c) An ACO whose participation agreement was previously terminated may reenter the program for a subsequent agreement period.

(1) If the termination occurred less than half way through the agreement period, an ACO that was previously under a one-sided model may reenter the program under the one-sided model or a two-sided model. If the ACO reenters the program under the one-sided model, the ACO will be considered to be in the same agreement period under the one-sided model as it was at the time of termination.

(2) If the termination occurred more than half way through the agreement period, an ACO that was previously in its first agreement period under the one-sided model may reenter the program under the one-sided model or a two-sided model. If the ACO reenters the program under the one-sided model, the ACO will be considered to be in its second agreement period under the one-sided model. An ACO that was previously in its second agreement period under the one-sided model must reenter the program under a two-sided model.

(3) Regardless of the date of termination, an ACO that was previously under a two-sided model may only reapply for participation in a two-sided model.

■ 23. Add § 425.224 to subpart C to read as follows:

§ 425.224 Renewal of participation agreements.

(a) *General rules.* An ACO may request renewal of its participation agreement for a second or subsequent agreement period.

(1) In order to obtain a determination regarding whether it meets the requirements for renewal of its

participation agreement, the ACO must submit a complete renewal request in the form and manner and by the deadline specified by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the renewal request is accurate, complete, and truthful.

(3) An ACO that seeks renewal of its participation agreement and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of its renewal request with the Antitrust Agencies.

(b) *Review of renewal request.* (1) CMS determines whether to renew a participation agreement based on an evaluation of all of the following factors:

(i) Whether the ACO satisfies the criteria for operating under the selected risk track.

(ii) The ACO’s history of compliance with the requirements of the Shared Savings Program.

(iii) Whether the ACO has established that it is in compliance with the eligibility and other requirements of the Shared Savings Program, including the ability to repay losses, if applicable.

(iv) Whether the ACO met the quality performance standard during at least 1 of the first 2 years of the previous agreement period.

(v) For ACOs under a two-sided model, whether the ACO has repaid losses owed to the program that it generated during the first 2 years of the previous agreement period.

(vi) The results of a program integrity screening of the ACO, its ACO participants, and its ACO providers/suppliers (conducted in accordance with § 425.304(b)).

(2) Renewal requests are approved or denied on the basis of the following information:

(i) Information contained in and submitted with the renewal request by a deadline specified by CMS.

(ii) Supplemental information that was submitted by a deadline specified by CMS in response to a CMS request for information.

(iii) Other information available to CMS.

(3) CMS notifies the ACO when supplemental information is required for CMS to make such a determination and provides an opportunity for the ACO to submit the information.

(c) *Notice of determination.* (1) CMS notifies the ACO in writing of its determination to approve or deny the ACO’s renewal request.

(2) If CMS denies the renewal request, the notice of determination—

- (i) Specifies the reasons for the denial; and
- (ii) Informs the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

§ 425.304 [Amended]

- 24. Amend § 425.304 by removing paragraph (d).
- 25. Revise § 425.306 to read as follows:

§ 425.306 Participant agreement and exclusivity of ACO participants.

(a) Each ACO participant must commit to the term of the participation agreement and sign an ACO participant agreement that complies with the requirements of this part.

(b)(1) Except as specified in paragraph (b)(2) of this section, ACO participants are not required to be exclusive to one Shared Savings Program ACO.

(2) Each ACO participant that submits claims for primary care services used to determine the ACO's assigned population under subpart E of this part must be exclusive to one Shared Savings Program ACO.

- 26. Revise § 425.308 to read as follows:

§ 425.308 Public reporting and transparency.

(a) *ACO public reporting Web page.* Each ACO must create and maintain a dedicated Web page on which it publicly reports the information set forth in paragraph (b) of this section. The ACO must report the address of such Web page to CMS in a form and manner specified by CMS and must notify CMS of changes to the web address in the form and manner specified by CMS.

(b) *Information to be reported.* The ACO must publicly report the following information in a standardized format specified by CMS:

- (1) Name and location.
- (2) Primary contact.
- (3) Organizational information, including all of the following:
 - (i) Identification of ACO participants.
 - (ii) Identification of participants in joint ventures between ACO professionals and hospitals.
 - (iii) Identification of the members of its governing body.
 - (iv) Identification of key clinical and administrative leadership.
 - (v) Identification of associated committees and committee leadership.
 - (vi) Identification of the types of ACO participants or combinations of ACO participants (as listed in § 425.102(a)) that formed the ACO.
- (4) Shared savings and losses information, including the following:

(i) Amount of any payment of shared savings received by the ACO or shared losses owed to CMS.

(ii) Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.

(5) The ACO's performance on all quality measures.

(6) Use of payment rule waivers under § 425.612, if applicable.

(c) *Approval of public reporting information.* Information reported on an ACO's public reporting Web page in compliance with the requirements of the standardized format specified by CMS is not subject to marketing review and approval under § 425.310.

(d) *Public reporting by CMS.* CMS may publicly report ACO-specific information, including but not limited to the ACO public reporting Web page address and the information required to be publicly reported under paragraph (b) of this section.

- 27. Amend § 425.312, effective November 1, 2015, by revising paragraph (a) and removing and reserving paragraph (b).

The revision reads as follows:

§ 425.312 Notification to beneficiaries of participation in the shared savings program.

(a) ACO participants must notify beneficiaries at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program and of the opportunity to decline claims data sharing under § 425.708.

(1) Notification is carried out when an ACO participant posts signs in its facilities and, in settings in which beneficiaries receive primary care services, by making standardized written notices available upon request.

(2) The ACO must use template language developed by CMS for notifications described in paragraph (a)(1) of this section.

* * * * *

§ 425.314 [Amended]

- 28. Amend § 425.314 (c) by removing the term "agreement" and adding in its place the terms "participation agreement".

§ 425.316 [Amended]

- 29. Amend § 425.316 by:
 - A. Removing paragraphs (c)(3) and (4).
 - B. Redesignating paragraph (c)(5) as (c)(3).

■ C. In newly redesignated paragraph (c)(3) by removing the phrase "fully and completely" and adding in its place the phrase "accurately, completely, and timely".

- 30. Amend § 425.400 by—

- A. Adding paragraph (a)(1) introductory text.
- B. Revising paragraph (a)(1)(i).
- C. In paragraph (a)(1)(ii), by removing the phrase "by a physician who is an ACO provider/supplier during the performance year" and adding in its place the phrase "by a physician who is an ACO professional during each performance year".
- D. Adding paragraph (a)(2) subject heading and paragraph (a)(3).

The additions read as follows:

§ 425.400 General.

(a)(1) *General.* CMS employs the assignment methodology described in § 425.402 and § 425.404 for purposes of benchmarking, preliminary prospective assignment (including quarterly updates), retrospective reconciliation, and prospective assignment.

(i) A Medicare fee-for-service beneficiary is assigned to an ACO if the—

(A) Beneficiary meets the eligibility criteria under § 425.401(a); and

(B) Beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402 and § 425.404.

* * * * *

(2) *Assignment under Tracks 1 and 2.*

* * * * *

(3) *Prospective assignment under Track 3.* (i) Medicare fee-for-service beneficiaries are prospectively assigned to an ACO under Track 3 at the beginning of each benchmark or performance year based on the beneficiary's use of primary care services in the most recent 12 months for which data are available, using the assignment methodology described in §§ 425.402 and 425.404.

(ii) Beneficiaries that are prospectively assigned to an ACO under paragraph (a)(3)(i) of this section will remain assigned to the ACO at the end of the benchmark or performance year unless they meet any of the exclusion criteria under § 425.401(b).

* * * * *

- 31. Add § 425.401 to read as follows:

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

(a) A beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if

the beneficiary meets all of the following criteria during the assignment window:

- (1)(i) Has at least 1 month of Part A and Part B enrollment; and
- (ii) Does not have any months of Part A only or Part B only enrollment.
- (2) Does not have any months of Medicare group (private) health plan enrollment.
- (3) Is not assigned to any other Medicare shared savings initiative.
- (4) Lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

(b) A beneficiary will be excluded from the prospective assignment list of an ACO participating under Track 3 at the end of a performance or benchmark year and quarterly during each performance year, if the beneficiary meets any of the following criteria during the performance or benchmark year:

- (1)(i) Does not have at least 1 month of Part A and Part B enrollment; and
- (ii) Has any months of Part A only or Part B only enrollment.
- (2) Has any months of Medicare group (private) health plan enrollment.
- (3) Did not live in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

■ 32. Amend § 425.402 by:

■ A. Revising paragraph (a) introductory text.

■ B. In paragraphs (a)(1)(ii) introductory text and (a)(1)(ii)(A) by removing the phrase "ACO providers/suppliers" and adding in its place the phrase "ACO professionals".

■ C. In paragraphs (a)(2) introductory text and (a)(2)(i) by removing the phrase "ACO professionals who are ACO providers/suppliers in" and adding in its place the phrase "ACO professionals in".

■ D. Adding paragraphs (b) and (c).

The revision and additions read as follows:

§ 425.402 Basic assignment methodology.

(a) For performance years 2012 through 2015, CMS employs the following step-wise methodology to assign Medicare beneficiaries to an ACO after identifying all patients that had at least one primary care service with a physician who is an ACO professional of that ACO:

* * * * *

(b) For performance year 2016 and subsequent performance years, CMS

employs the following step-wise methodology to assign Medicare fee-for-service beneficiaries to an ACO:

(1) Identify all beneficiaries that had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or who has one of the primary specialty designations included in paragraph (c) of this section.

(2) Identify all primary care services furnished to beneficiaries identified in paragraph (b)(1) of this section by ACO professionals of that ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in paragraph (c) of this section during the applicable assignment window.

(3) Under the first step, a beneficiary identified in paragraph (b)(1) of this section is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are—

- (i) ACO professionals in any other ACO; or
- (ii) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(4) The second step considers the remainder of the beneficiaries identified in paragraph (b)(1) of this section who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside the ACO or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by physicians who are ACO professionals with specialty designations as specified in paragraph (c) of this section are greater than the allowed charges for primary care services furnished by physicians with specialty designations as specified in paragraph (c) of this section—

- (i) Who are ACO professionals in any other ACO; or
- (ii) Who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

(c) ACO professionals considered in the second step of the assignment methodology in paragraph (b)(4) of this section include physicians who have one of the following primary specialty designations:

- (1) Cardiology.
- (2) Osteopathic manipulative medicine.
- (3) Neurology.
- (4) Obstetrics/gynecology.
- (5) Sports medicine.
- (6) Physical medicine and rehabilitation.
- (7) Psychiatry.
- (8) Geriatric psychiatry.
- (9) Pulmonary disease.
- (10) Nephrology.
- (11) Endocrinology.
- (12) Multispecialty clinic or group practice.
- (13) Addiction medicine.
- (14) Hematology.
- (15) Hematology/oncology.
- (16) Preventive medicine.
- (17) Neuropsychiatry.
- (18) Medical oncology.
- (19) Gynecology/oncology.

■ 33. Amend § 425.404 by revising paragraph (b) to read as follows:

§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.

* * * * *

(b) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service —

(1) If the claim includes a HCPCS or revenue center code that meets the definition of primary care services under § 425.20;

(2) Performed by a primary care physician if the NPI of a physician identified in the attestation provided under paragraph (a) of this section is reported on the claim for a primary care service (as described in paragraph (b)(1) of this section) as the attending provider; and

(3) Performed by a non-physician ACO professional if the NPI reported on the claim for a primary care service (as described in paragraph (b)(1) of this section) as the attending provider is an ACO professional but is not identified in the attestation provided under paragraph (a) of this section.

■ 34. Amend § 425.600 by:

■ A. In paragraph (a)(2), by removing the phrase "under the two-sided model" and adding in its place the phrase "under a two-sided model".

■ B. Adding paragraph (a)(3).

■ C. Revising paragraph (b).

■ D. In paragraph (c) by removing the phrase "net loss during the initial agreement period may reapply" and adding in its place the phrase "net loss during a previous agreement period may reapply".

The addition and revision read as follows:

§ 425.600 Selection of risk model.

(a) * * *

(3) *Track 3.* Under Track 3, the ACO operates under a two-sided model (as described under § 425.610), sharing both savings and losses with the Medicare program for the agreement period.

(b) ACOs may operate under the one-sided model for a maximum of two agreement periods. An ACO may not operate under the one-sided model for a second agreement period unless the—

(1) Immediately preceding agreement period was under the one-sided model; and

(2) The ACO meets the criteria established for ACOs seeking to renew their agreements under § 425.224(b).

* * * * *

■ 35. Amend § 425.602 as follows:

■ A. By revising the section heading.

■ B. In paragraph (a)(7) introductory text by removing the phrase “Weights each year of the benchmark using” and adding in its place the phrase “Weights each year of the benchmark for the initial agreement period using”.

■ C. In paragraph (a)(8) by removing the phrase “The ACO’s benchmark may be adjusted” and adding in its place the phrase “The ACO’s benchmark will be adjusted in accordance with § 425.118(b)”.

■ D. By revising paragraph (c).

The revisions read as follows:

§ 425.602 Establishing, updating, and resetting the benchmark.

* * * * *

(c) *Resetting the benchmark.* (1) An ACO’s benchmark will be reset at the start of each subsequent agreement period.

(2) When resetting the ACO’s benchmark for a subsequent agreement period—

(i) Each benchmark year will be weighted equally

(ii) An adjustment will be made to account for the average per capita amount of savings generated during the ACO’s previous agreement period. The adjustment will be limited to the average number of assigned beneficiaries (expressed as person years) under the ACO’s previous agreement period.

■ 36. Amend § 425.606 as follows:

■ A. By revising the section heading.

■ B. In paragraph (a) introductory text, by removing the phrase “under the two-sided model,” and adding in its place the phrase “under Track 2,”

■ C. By revising paragraph (b).

■ D. In paragraph (d), by removing the phrase “under the two-sided model” and adding in its place the phrase “under Track 2”.

■ E. In paragraph (e)(2), by removing the phrase “under the two-sided model”

and adding in its place the phrase “under Track 2”.

■ F. In paragraph (g)(1), by removing the phrase “in a two-sided model” and adding in its place the phrase “in Track 2”.

The revisions read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(b) *Minimum savings or loss rate.*

(1)(i) For agreement periods beginning in 2012 through 2015, the ACO’s MSR and MLR are set at 2 percent.

(ii) For agreement periods beginning in 2016 and subsequent years, as part of the ACO’s application for, or renewal of, program participation, the ACO must choose from the following options for establishing the MSR/MLR for the duration of the agreement period:

(A) Zero percent MSR/MLR.

(B) Symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent.

(C) Symmetrical MSR/MLR that varies, based on the number of beneficiaries assigned to the ACO under subpart E of this part. The MSR for an ACO under Track 2 is the same as the MSR that would apply in the one-sided model under § 425.604(b) and is based on the number of assigned beneficiaries. The MLR under Track 2 is equal to the negative MSR.

(2) To qualify for shared savings under Track 2, an ACO’s average per capita Medicare expenditures for the performance year must be below its updated benchmark costs for the year by at least the MSR established for the ACO.

(3) To be responsible for sharing losses with the Medicare program, an ACO’s average per capita Medicare expenditures for the performance year must be above its updated benchmark costs for the year by at least the MLR established for the ACO.

* * * * *

■ 37. Add § 425.610 to subpart G to read as follows:

§ 425.610 Calculation of shared savings and losses under Track 3.

(a) *General rule.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are above or below the updated benchmark determined under § 425.602. In order to qualify for a shared savings payment under Track 3, or to be responsible for sharing losses with CMS, an ACO’s average per capita Medicare expenditures under the ACO for

Medicare fee-for-service beneficiaries for Parts A and B services for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section.

(1) *Newly assigned beneficiaries.* CMS uses an ACO’s HCC prospective risk score to adjust for changes in severity and case mix in this population.

(2) *Continuously assigned beneficiaries.* (i) CMS uses demographic factors to adjust for changes in the continuously assigned beneficiary population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS adjusts for changes in severity and case mix for this population using this lower prospective HCC risk score.

(3) Assigned beneficiary changes in demographics and health status are used to adjust benchmark expenditures as described in § 425.602(a). In adjusting for health status and demographic changes CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary’s total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(5) CMS uses a 3-month claims run out with a completion factor to calculate an ACO’s per capita expenditures for each performance year.

(6) Calculations of the ACO’s expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO’s average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings or loss rate.* (1) As part of the ACO's application for, or renewal of, program participation, the ACO must choose from the following options for establishing the MSR/MLR for the duration of the agreement period:

(i) Zero percent MSR/MLR
(ii) Symmetrical MSR/MLR in a 0.5 percent increment between 0.5–2.0 percent.

(iii) Symmetrical MSR/MLR that varies, based on the number of beneficiaries assigned to the ACO under subpart E of this part. The MSR for an ACO under Track 3 is the same as the MSR that would apply in the one-sided model under § 425.604(b) and is based on the number of assigned beneficiaries. The MLR under Track 3 is equal to the negative MSR.

(2) To qualify for shared savings under Track 3, an ACO's average per capita Medicare expenditures for the performance year must be below its updated benchmark costs for the year by at least the MSR established for the ACO.

(3) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must be above its updated benchmark costs for the year by at least the MLR established for the ACO.

(c) *Qualification for shared savings payment.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under Track 3 will receive a shared savings payment of up to 75 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under Track 3 may not exceed 20 percent of its updated benchmark.

(f) *Shared loss rate.* The shared loss rate—

(1) For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses

is determined based on the inverse of its final sharing rate described in § 425.610(d) (that is, 1 minus the final shared savings rate determined under § 425.610(d));

(2) May not exceed 75 percent; and
(3) May not be less than 40 percent.

(g) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed 15 percent of its updated benchmark as determined under § 425.602.

(h) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

■ 38. Add § 425.612 to subpart G to read as follows:

§ 425.612 Waivers of payment rules or other Medicare requirements.

(a) *General.* CMS may waive certain payment rules or other Medicare requirements as determined necessary to carry out the Shared Savings Program under this part.

(1) *SNF 3-day rule.* For performance year 2017 and subsequent performance years, CMS waives the requirement in section 1861(i) of the Act for a 3-day inpatient hospital stay prior to a Medicare-covered post-hospital extended care service for eligible beneficiaries prospectively assigned to ACOs participating in Track 3 that receive otherwise covered post-hospital extended care services furnished by an eligible SNF that has entered into a written agreement to partner with the ACO for purposes of this waiver. All other provisions of the statute and regulations regarding Medicare Part A post-hospital extended care services continue to apply.

(i) ACOs must submit to CMS supplemental application information sufficient to demonstrate the ACO has the capacity to identify and manage beneficiaries who would be either directly admitted to a SNF or admitted to a SNF after an inpatient hospitalization of fewer than 3-days in the form and manner specified by CMS. Application materials include but are not limited to, the following:

(A) Narratives describing how the ACO plans to implement the waiver. Narratives must include the following:

(1) The communication plan between the ACO and its SNF affiliates.

(2) A care management plan for beneficiaries admitted to a SNF affiliate.

(3) A beneficiary evaluation and admission plan approved by the ACO medical director and the healthcare professional responsible for the ACO's quality improvement and assurance processes under § 425.112.

(4) Any financial relationships between the ACO, SNF, and acute care hospitals.

(B) A list of SNFs with whom the ACO will partner along with executed written SNF affiliate agreements between the ACO and each listed SNF.

(C) Documentation demonstrating that each SNF included on the list provided under paragraph (a)(1)(i)(B) of this section has an overall rating of 3 or higher under the CMS 5-star Quality Rating System.

(ii) In order to be eligible to receive covered SNF services under the waiver, a beneficiary must meet the following requirements:

(A) Is prospectively assigned to the ACO for the performance year in which they are admitted to the eligible SNF.

(B) Does not reside in a SNF or other long-term care setting.

(C) Is medically stable.

(D) Does not require inpatient or further inpatient hospital evaluation or treatment.

(E) Have certain and confirmed diagnoses.

(F) Have an identified skilled nursing or rehabilitation need that cannot be provided as an outpatient.

(G) Have been evaluated and approved for admission to the SNF within 3 days prior to the SNF admission by an ACO provider/supplier who is a physician, consistent with the ACO's beneficiary evaluation and admission plan.

(iii) SNFs eligible to partner and enter into written agreements with ACOs for purposes of this waiver must do the following:

(A) Have and maintain an overall rating of 3 or higher under the CMS 5-star Quality Rating System.

(B) Sign a SNF affiliate agreement with the ACO that includes elements determined by CMS including but not limited to the following:

(1) Agreement to comply with the requirements and conditions of this part, including but not limited to those specified in the participation agreement with CMS.

(2) Effective dates of the SNF affiliate agreement.

(3) Agreement to implement and comply with the ACO's beneficiary evaluation and admission plan and the care management plan.

(4) Agreement to validate the eligibility of a beneficiary to receive

covered SNF services in accordance with the waiver prior to admission.

(5) Remedial processes and penalties that will apply for non-compliance.

(2) [Reserved].

(b) *Review and determination of request to use waivers.* (1) In order to obtain a determination regarding whether the ACO may use waivers under this section, an ACO must submit a waiver request to CMS in the form and manner and by a deadline specified by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the waiver request submitted under paragraph (b)(1) of this section is accurate, complete, and truthful.

(3) CMS evaluates an ACO's waiver request to determine whether it satisfies the requirements of this part and approves or denies waiver requests accordingly. Waiver requests are approved or denied on the basis of the following:

(i) Information contained in and submitted with the waiver request by a deadline specified by CMS.

(ii) Supplemental information submitted by a deadline specified by CMS in response to a CMS request for information.

(iii) Screening of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities providing services to Medicare beneficiaries in accordance with the terms of the waiver.

(iv) Other information available to CMS.

(4) CMS may deny a waiver request if an ACO fails to submit requested information by the deadlines established by CMS.

(c) *Effective and termination date of waivers.* (1) Waivers are effective upon CMS notification of approval for the waiver or the start date of the participation agreement, whichever is later.

(2) Waivers do not extend beyond the end of the participation agreement.

(3) If CMS terminates the participation agreement under § 425.218, the waiver ends on the date specified by CMS in the termination notice.

(4) If the ACO terminates the participation agreement, the waiver ends on the effective date of termination as specified in the written notification required under § 425.220.

(d) *Monitoring and termination of waivers.* (1) ACOs with approved waivers are required to post their use of

the waiver as part of public reporting under § 425.308.

(2) CMS monitors and audits the use of such waivers in accordance with § 425.316.

(3) CMS reserves the right to deny or revoke a waiver if an ACO, its ACO participants, ACO providers/suppliers or other individuals or entities providing services to Medicare beneficiaries are not in compliance with the requirements of this part or if any of the following occur:

(i) The waiver is not used as described in the ACO's waiver request under paragraph (b)(1) of this section.

(ii) The ACO does not successfully meet the quality reporting standard under subpart F of this part.

(iii) CMS identifies a program integrity issue affecting the ACO's use of the waiver.

(e) *Other rules governing use of waivers.* (1) Waivers under this section do not protect financial or other arrangements between or among ACOs, ACO participants, ACO providers/suppliers, or other individual or entities providing services to Medicare beneficiaries from liability under the fraud and abuse laws or any other applicable laws.

(2) Waivers under this section do not protect any person or entity from liability for any violation of law or regulation for any conduct other than the conduct permitted by a waiver under paragraph (a) of this section.

(3) ACOs must ensure compliance with all claims submission requirements, except those expressly waived under paragraph (a) of this section.

■ 39. Amend § 425.702 by:

■ A. Redesignating paragraphs (c)(1) introductory text, (c)(1)(i), (c)(1)(ii), (c)(1)(iii), and (c)(1)(iv) as paragraphs (c)(1)(i) introductory text, (c)(1)(i)(A), (c)(1)(i)(B), (c)(1)(i)(C), and (c)(1)(i)(D), respectively.

■ B. In newly redesignated paragraph (c)(1)(i) introductory text by removing the phrase "At the beginning" and adding in its place the phrase "For performance years 2012 through 2015, at the beginning".

■ C. Adding paragraph (c)(1)(ii).

The addition reads as follows:

§ 425.702 Aggregate reports.

* * * * *

(c) * * *

(1) * * *

(ii) For performance year 2016 and subsequent performance years, at the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year,

CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, process development, case management, and care coordination, provides the ACO with information about its fee-for-service population.

(A) Under Tracks 1 and 2, the following information is made available regarding preliminarily prospectively assigned beneficiaries and beneficiaries that received a primary care service during the previous 12 months from one of the ACO participants that submits claims for primary care services used to determine the ACO's assigned population under subpart E of this part:

(1) Beneficiary name.

(2) Date of birth.

(3) Health Insurance Claim Number (HICN).

(4) Sex.

(B) Under Tracks 1 and 2, information in the following categories, which represents the minimum data necessary for ACOs to conduct health care operations work is made available regarding preliminarily prospectively assigned beneficiaries:

(1) Demographic data such as enrollment status.

(2) Health status information such as risk profile and chronic condition subgroup.

(3) Utilization rates of Medicare services such as the use of evaluation and management, hospital, emergency, and post-acute services, including the dates and place of service.

(4) Expenditure information related to utilization of services.

(C) The information under paragraphs (c)(1)(ii)(A) and (c)(1)(ii)(B) of this section will be made available to ACOs in Track 3, but will be limited to the ACO's prospectively assigned beneficiaries.

* * * * *

■ 40. Amend § 425.704, effective January 1, 2016, by:

■ A. Revising the section heading.

■ B. In the introductory text, by removing the phrase "claims data for preliminary prospectively assigned beneficiaries" and adding in its place the phrase "claims data for preliminarily prospectively and prospectively assigned beneficiaries".

■ C. In the introductory text, by removing the phrase "upon whom assignment is based during the agreement period" and adding in its place the phrase "that submits claims for primary care services used to determine the ACO's assigned population under subpart E of this part during the performance year".

■ D. In paragraph (a) by removing the phrase “ACOs may request data as often” and adding in its place “ACOs may access requested data as often”.

■ E. Revising paragraph (d)(1).

■ F. In paragraph (d)(2) by removing the phrase “has been notified in writing how the ACO intends to use” and adding in its place the phrase “has been notified in compliance with § 425.708 that the ACO has requested access to”.

The revisions read as follows:

§ 425.704 Beneficiary-identifiable claims data.

* * * * *

(d) * * *

(1) For an ACO participating—

(i) In Track 1 or 2, the beneficiary’s name appears on the preliminary prospective assignment list provided to the ACO at the beginning of the performance year, during each quarter (and in conjunction with the annual reconciliation) or the beneficiary has received a primary care service from an ACO participant upon whom assignment is based (under subpart E of this part) during the most recent 12-month period.

(ii) In Track 3, the beneficiary’s name appears on the prospective assignment list provided to the ACO at the beginning of the performance year.

* * * * *

■ 41. Amend § 425.708, effective November 1, 2015, by:

■ A. Revising the section heading and paragraph (a).

■ B. Removing paragraphs (b) and (c).

■ C. Redesignating paragraphs (d) through (f) as paragraphs (b) through (d), respectively.

■ D. Revising newly redesignated paragraphs (b) and (c).

■ The revisions read as follows:

§ 425.708 Beneficiaries may decline claims data sharing.

(a) Beneficiaries must receive notification about the Shared Savings Program and the opportunity to decline claims data sharing and instructions on how to inform CMS directly of their preference.

(1) FFS beneficiaries are notified about the opportunity to decline claims data sharing through CMS materials such as the Medicare & You Handbook and through the notifications required under § 425.312.

(2) The notifications provided under § 425.312 must state that the ACO may have requested beneficiary identifiable claims data about the beneficiary for purposes of its care coordination and quality improvement work, and inform the beneficiary how to decline having his or her claims information shared with the ACO in the form and manner specified by CMS.

(3) Beneficiary requests to decline claims data sharing will remain in effect unless and until a beneficiary subsequently contacts CMS to amend that request to permit claims data sharing with ACOs.

(b) The opportunity to decline having claims data shared with an ACO under paragraph (a) of this section does not apply to the information that CMS provides to ACOs under § 425.702(c).

(c) In accordance with 42 U.S.C. 290dd–2 and the implementing regulations at 42 CFR part 2, CMS does not share beneficiary identifiable claims data relating to the diagnosis and

treatment of alcohol and substance abuse without the explicit written consent of the beneficiary.

* * * * *

■ 42. Amend § 425.802 by revising paragraph (a)(2) to read as follows:

§ 425.802 Request for review.

(a) * * *

(2) The reconsideration review must be held on the record (review of submitted documentation).

* * * * *

■ 43. Amend § 425.804 by:

■ A. Revising paragraph (a)(3).

■ B. Removing paragraph (d).

■ C. Redesignating paragraphs (e) and (f) as paragraphs (d) and (e), respectively.

The revision reads as follows:

§ 425.804 Reconsideration review process.

(a) * * *

(3) A briefing schedule that permits each party to submit only one written brief, including any evidence, for consideration by the reconsideration official in support of the party’s position. The submission of any additional briefs or supplemental evidence will be at the sole discretion of the reconsideration official.

* * * * *

Dated: May 19, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: May 21, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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