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Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS–1345–F]

RIN 0938–AQ22

Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

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

ACTION: Final rule.

SUMMARY: This final rule implements section 3022 of the Affordable Care Act which contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program. Under these provisions, providers of services and suppliers can continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, and be eligible for additional payments if they meet specified quality and savings requirements.

DATES: These regulations are effective on January 3, 2012.

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SUPPLEMENTARY INFORMATION:

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Regulations Text

Acronyms

ACO Accountable Care Organization
AHRQ Agency for Healthcare Research and Quality
BAA Business Associate Agreements
BCBSMA Blue Cross Blue Shield of Massachusetts
BIPA Benefits Improvement and Protection Act
CAD Coronary Artery Disease
CAHPS Consumer Assessment of Health Providers and Systems
CAHs Critical Access Hospitals
CBIC Competitive Bidding Implementation Contractor
CBSA Core Based Statistical Area
CHCs Community Health Centers
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
COPD Chronic Obstructive Pulmonary Disease
CP Certified Psychologist
CSW Clinical Social Worker
CWF Common Working File
DHHS Department of Health and Human Services
DOB Date of Birth
DOJ Department of Justice
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DSH Disproportionate Share Hospital
DUA Data use Agreement
E&M Evaluation and Management
EHR Electronic Health Record
ESRD End Stage Renal Disease
eRx Electronic Prescribing Incentive Program
FFS Fee-for-service
FQHCs Federally Qualified Health Centers
FTC Federal Trade Commission
GAO Government Accountability Office
GPCI Geographic Practice Cost Index
GPRO Group Practice Reporting Option
HAC Hospital Acquired Conditions
HCAHPS Hospital Consumer Assessment of Health care Provider and Systems
HCC Hierarchal Condition Category
HCPCS Healthcare Common Procedure Coding System
HHAs Home Health Agencies
HICN Health Insurance Claim Number
HIPAA Heath Insurance Portability and Accountability Act of 1996
HIE Health Information Exchange
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
HMO Health Maintenance Organization
HRSA Health Resources and Services Administration
HVBP Hospital Value Based Purchasing
IME Indirect Medical Education
IOM Institute of Medicine
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
IRS Internal Revenue Service
LTCHs Long-Term Acute Care Hospitals
MA Medicare Advantage
MAPCP Multipayer Advanced Primary Care Practice
MedPAC Medicare Payment Advisory Commission
MHCQ Medicare Health Care Quality
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MS–DRGs Medicare Severity-Adjusted Diagnosis Related Groups
MSP Minimum Savings Percentage
MSR Minimum Savings Rate
NCQA National Committee for Quality Assurance
NCCCN North Carolina Community Care Network
NP Nurse Practitioner
NPI National Provider Identifier
NQF National Quality Forum
OIG Office of Inspector General
OMB Office of Management and Budget
PA Physician Assistant
PACE Program of All Inclusive Care for the Elderly
PACFs Post-Acute Care Facilities
PCMH Patient Centered Medical Home
PFS Physician Fee Schedule
PGP Physician Group Practice
PHI Protected health information
POS Point of Service
PPO Preferred provider organization
PPS Prospective Payment System
PQRI Physician Quality Reporting Initiative
PQRS Physician Quality Reporting System
PRA Paperwork Reduction Act
PSA Primary Service Areas
RFI Request for Information
RHCs Rural Health Clinics
RIA Regulatory Impact Analysis
SNFs Skilled Nursing Facilities
SSA Social Security Administration
SSN Social Security Number
TIN Taxpayer Identification Number

I. Background

A. Introduction and Overview of Value-Based Purchasing

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 Public Law 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 program integrity within Medicare, and put Medicare on a firmer financial footing.

Many provisions within the Affordable Care Act implement value-based purchasing programs; section 3022 requires the Secretary to establish the Medicare Shared Savings Program (Shared Savings Program), intended to encourage the development of Accountable Care Organizations (ACOs) in Medicare. The Shared Savings 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 aimed at: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in Medicare Parts A and B expenditures. We refer to this approach throughout this final rule as the three-part aim.

Value-based purchasing is a concept that links payment directly to the quality of care provided and is a strategy that can help transform the current payment system by rewarding providers for delivering high quality, efficient clinical care. In the April 7, 2011 **Federal Register** (76 FR 19528), we published the Shared Savings Program proposed rule. In the proposed rule, we

discussed our experience implementing value based purchasing concepts. In addition to improving quality, value-based purchasing initiatives seek to reduce growth in health care expenditures.

We view value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely increased volume. For a complete discussion, including our goals in implementing value-based purchasing initiatives, please refer to section I.A. of the proposed rule (76 FR 19530).

B. Statutory Basis for the Medicare Shared Savings Program

Section 3022 of the Affordable Care Act amended Title XVIII of the Social Security Act (the Act) (42 U.S.C. 1395 *et seq.*) by adding new section 1899 to the Act to establish a Shared Savings Program that promotes accountability for a patient population, coordinates items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. A detailed summary of the provisions within section 3022 of the Affordable Care Act is in section I.B. of the proposed rule (see 76 FR 19531).

C. Overview of the Medicare Shared Savings Program

The intent 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 incent higher value care. As an incentive to ACOs that successfully meet quality and savings requirements, the Medicare Program can share a percentage of the achieved savings with the ACO. Under the Shared Savings Program, ACOs will only share in savings if they meet both the quality performance standards and generate shareable savings. In order to fulfill the intent of the Shared Savings Program as established by the Affordable Care Act, we stated in the proposed rule that we will focus on achieving the three-part aim consisting of: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in expenditures.

In developing the Shared Savings Program, and in response to stakeholder suggestions, we have worked very closely with agencies across the Federal government to develop policies to encourage participation and ensure a coordinated and aligned inter- and intra-agency program implementation. The result of this effort is the release of several documents that potential participants are strongly encouraged to review. These documents are described in more detail in section II.C.5. of this final rule, and include: (1) A joint CMS and DHHS OIG interim final rule with comment period published elsewhere in this issue of the **Federal Register** entitled Medicare Program; Final Waivers in Connection With the Shared Savings Program; (2) IRS Notice 2011–20 and other applicable IRS guidance viewable on www.irs.gov; and (3) a Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program issued by the FTC and DOJ (collectively, the Antitrust Agencies).

In this final rule we have made significant modifications to reduce burden and cost for participating ACOs. These modifications include: (1) Greater flexibility in eligibility to participate in the Shared Savings Program; (2) multiple start dates in 2012; (3) establishment of a longer agreement period for those starting in 2012; (4) greater flexibility in the governance and legal structure of an ACO; (5) simpler and more streamlined quality performance standards; (6) adjustments to the financial model to increase financial incentives to participate; (7) increased sharing caps; (8) no down-side risk and first-dollar sharing in Track 1; (9) removal of the 25 percent withhold of shared savings; (10) greater flexibility in timing for the evaluation of sharing savings (claims run-out reduced to 3 months); (11) greater flexibility in antitrust review; and (12) greater flexibility in timing for repayment of losses; and (13) additional options for participation of FQHCs and RHCs.

D. Public Comments Received on the Proposed Rule

We received approximately 1,320 public comments on the April 7, 2011 proposed rule (76 FR 19528). These public comments addressed issues on multiple topics and here, rather than throughout the regulation, we extend our great appreciation for the input. We received some comments that were outside the scope of the proposed rule and therefore not addressed in this final rule (for example, suggested changes to the physician fee schedule, or suggestions on other Affordable Care Act provisions). Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. In this final rule, we have organized the document by presenting our proposals, summarizing and responding to the public comment for the proposal(s), and describing our final policy.

Comment: We received comments expressing support for the proposed design of the Shared Savings Program, as well as comments disagreeing with it. Those in disagreement generally found the proposed requirements to be too prescriptive and burdensome. Other commenters expressed their disagreement with a program they perceive as limiting access to necessary care.

Response: We appreciate all the feedback we received. We have been encouraged by the level of engagement by stakeholders in this rulemaking process. We thank all of the commenters for helping us develop the Shared Savings Program. Where possible we have tried to reduce or eliminate prescriptive or burdensome requirements that could discourage participation in the Shared Savings Program. We have also been vigilant in protecting the rights and benefits of FFS beneficiaries under traditional Medicare to maintain the same access to care and freedom of choice that existed prior to the implementation of this program. These provisions can be found throughout this final rule.

Comment: Two commenters encouraged CMS to make the PGP demonstration a national program. In contrast, a few commenters stated concern about insufficient testing of the Shared Savings Program as a demonstration program prior to this final rule. The commenters acknowledged the PGP demonstration as the precursor, but stated that our proposals deviated too far from the PGP demonstration. One commenter noted the PGP demonstration consisted of large health organizations that had access to $1.75 million in capital and while half of the participants shared in savings, none had a complete return on their investment. They suggested that CMS continue to create demonstration projects for shared savings initiatives and delay the implementation of the Shared Savings Program. One commenter suggested phasing in the program. Specifically, the commenter suggested that we start small and periodically assess the program's requirements to determine which policies promote success and which create barriers.

Response: The Shared Savings Program adopts many of the program aspects of the PGP demonstration, but some adjustments were necessary in

order to create a national program. We removed a few of the proposed deviations from the PGP demonstration from this final rule. For example, under the policies we are implementing in this final rule, Shared Savings Program participants may choose to enter a ''shared savings'' only track that will not require repayment of losses. The statute does not authorize us to delay the establishment of the Shared Savings Program. But, it is important to note that the Shared Savings Program is a voluntary program. Organizations that are not ready to participate can begin the transition towards a more coordinated delivery system, incorporating policies that promote success for the early participants and join the program at such time as they are ready. Additionally, the Innovation Center will continue to test program models that may influence policies adopted for future agreement periods for the Shared Savings Program. We intend to assess the policies for the Innovation Center's models and the Shared Savings Program to determine how well they are working and if there are any modifications that would enhance them.

Comment: One commenter expressed concern that we appeared to be limiting participation in the Shared Savings Program to 5 million beneficiaries and 100 to 200 ACOs.

Response: We assume this commenter was referring to the Regulatory Impact Analysis section of our proposed rule where our Office of the Actuary estimated that up to 5 million beneficiaries would receive care from providers participating in ACOs. That figure was an estimate based on the proposed program requirements and the anticipated level of interest and participation of providers based on the requirements. After making programmatic changes based on commenter feedback, we believe the policies implemented in this final rule will be more attractive to participants and have a positive impact on those estimates. Please note that as a voluntary national program, any and all groups of providers and suppliers that meet the eligibility criteria outlined in this final rule are invited to participate.

Comment: Many commenters requested CMS issue an interim final rule, rather than a final rule, in order to have flexibility to modify the proposals in the proposed rule. One commenter suggested the 60-day comment period did not provide enough time to analyze and comment on the proposed rule given the volume and complexity of the specific proposals as related to tribal health organizations and other public health providers.

Response: In the proposed rule, we not only outlined our proposals for implementing the Shared Savings Program, but also provided detailed information on other alternatives we had considered and we sought comment on both our proposed policies and the other alternatives. The public comments submitted in response to the proposed rule have provided us with additional information and background regarding not only our proposed policies, but also the alternatives we considered. In response to the public comments, we have made significant changes to a number of our proposed policies. Nevertheless, we believe the policies in this final rule remain consistent with the overall framework for the program initially laid out in the proposed rule. As a result, we do not believe that there is any benefit to publishing this rule as an interim final rule rather than a final rule. We also believe 60 days represented a sufficient amount of time for interested parties to submit their comments on the proposed rule. We received many detailed comments in response to the proposed rule within the 60-day comment period. We also note that a 60-day comment period is consistent with the requirements of section 1871(b)(1) of the Act and is the standard timeframe used for many of our proposed rules.

Comment: Many commenters were concerned that the Shared Savings Program has similar characteristics to some forms of managed care where it is possible to achieve savings through inappropriate reductions in patient care. Some commenters, for example, asserted that the Shared Savings Program is a capitated model that is not in the best interest of patients. Other commenters, such as beneficiaries and beneficiary advocates, indicated that beneficiaries should retain their right to see any doctor of their choosing. We also received comments expressing concern that, as with some managed care approaches, the Shared Savings program essentially transfers the locus of responsibility for health care away from the patient, which is not as effective as more consumer-driven approaches. Another commenter expressed concern that assignment of beneficiaries to an ACO participating in the Shared Savings Program indicates that the program is a new version of managed care. One commenter suggested using the current Medicare Advantage (MA) structure to serve as the foundation of the Shared Savings Program. The commenter argued that MA plans are better suited to take on risk and provide care that meets many of the goals of the Shared Savings Program, and allowing these entities to participate will enable the program to reach a larger population. Additionally, a commenter requested information on why CMS is creating new policies for compliance, marketing and ownership instead of using policies already in place by MA plans. A few commenters claimed other countries tried this model and failed.

Response: It is important to note that the Shared Savings Program is not a managed care 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 Shared Savings Program ''assignment'' methodology in no way implies a lock in or enrollment process. To the contrary, it is a process based exclusively on an assessment of where and from whom FFS beneficiaries have chosen to receive care during the course of each performance period. The 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 design of the Shared Savings Program places the patient at the center. It encourages physicians, through the eligibility requirements, to include their patients in decision making about their health care. While we frequently relied on our experience in other Medicare programs, including MA, to help develop program requirements for the Shared Savings Program, there are often times when the requirements deviate precisely because the intent of this program is not to recreate MA. Unlike MA, this program's design retains FFS flexibility and freedom of choice available under Medicare Parts A and B which necessitates different program requirements. Lastly, in order for an ACO to share in savings the ACO must meet quality standards and program requirements that we will be monitoring. We will monitor the ACO's compliance with these requirements, as described in section II.H. of this final rule, with a special focus on ACOs that attempt to avoid at-risk patients. The purpose of the Shared Savings Program is to achieve savings through improvements in the coordination and quality of care, and not through avoiding certain beneficiaries or placing limits on beneficiary access to needed care.

Comment: One commenter suggested CMS provide funding to Regional Health Improvement Collaboratives to assist in educating Medicare beneficiaries about the program and to help enable the collection and reporting of data on patient experience. In addition, one commenter recommended the creation of a national surveillance database during ACOs implementation to guide osteoporosis prevention, intervention and treatment efforts. The commenter suggested that a national database would help reduce mortality and costs associated with preventable hip fractures due to osteoporosis.

Response: Both are excellent suggestions. Unfortunately, we are not in a position to implement these recommendations for this program at this time. The comment suggesting funding for Regional Health Improvement Collaboratives is beyond the scope of the proposed rule. We note, however, that the Innovation Center is currently accepting innovative solutions aimed at improving care delivery at their Web site, *Innovations.cms.gov*.

Comment: One commenter suggested CMS address the comments received from the November 17, 2010 RFI.

Response: In the proposed rule, we summarized many of the comments we received in response to the RFI, and these comments informed many of the policy choices made in the proposed rule. In addition, the RFI comments are publicly available at *regulations.gov.* Accordingly, we will not be addressing the entirety of those comments in this final rule; however any RFI comments we determined pertinent to this final rule may appear.

Comment: One commenter expressed concern over CMS' example of reducing unnecessary hospital visits as one way that ACOs could improve care. The commenter explained that the excess revenue created by additional ER visits helps to sustain other services provided by a hospital that may not bring in as much revenue. The commenter concluded the reduction in visits would eventually lead to the closure of many small rural hospitals. A similar comment stated that encouraging coordination and reducing fragmented care will reduce hospital reimbursements.

Response: The focus of the Shared Savings Program is to provide coordinated care to Medicare FFS beneficiaries. The program aims to provide higher quality care across the continuum of care; this may include additional office visits, as opposed to ER visits, for patients who do not require emergency services. Cost shifting is of great concern to us both within the Shared Savings Program and outside of the program. We believe it is in the patient's best interest to receive care in the proper setting and to receive emergency services only in times of emergency. Incurring costs for unnecessary care, or care provided in an inappropriate care setting, can be harmful to beneficiaries and payers alike. For more information about cost shifting related to the Shared Savings Program refer to section II.H.4. of this final rule.

E. Reorganization of the Regulations Text

We have revised the proposed regulations text to reflect the final policies adopted in this final rule. We have also made significant revisions to the structure and organization of the regulations text in order to correspond more closely with the organization of the preamble to this final rule and to make it easier to locate specific provisions within the regulations text.

II. Provisions of the Proposed Rule, Summary of and Responses to Public Comments, and the Provisions of the Final Rule

A. Definitions

For purposes of the proposed rule, we defined three terms used throughout the discussion: Accountable care organization (ACO), ACO participant, and ACO provider/supplier. We encourage the reader to review these definitions in § 425.20. We incorporated comments on these definitions into the discussion that follows.

B. Eligibility and Governance

1. General Requirements

a. Accountability for Beneficiaries

Section 1899(b)(2)(A) of the Act requires participating ACOs to ''be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.'' To satisfy this requirement, we proposed that an ACO executive who has the authority to bind the ACO must certify to the best of his or her knowledge, information, and belief that the ACO participants are willing to become accountable for, and to report to us on, the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO. We further proposed that this certification would be included as part of the ACO's application and participation agreement.

Comment: A commenter suggested that providers should not be held liable for unmanageable patients and/or those patients that refuse treatment altogether. Other commenters recommended that we not hold an ACO accountable for those patients who choose to decline to have CMS share their claims data with the ACO. Another commenter suggested that CMS require ACOs to state specifically in their applications the processes used to assure that Medicare patients have access to relatively costly but medically necessary procedures, such as transplantation.

Response: In order to retain beneficiary freedom of choice under traditional FFS Medicare, the basis for beneficiary assignment to ACOs is where, and from whom, they choose to receive a plurality of their primary care services during the performance year. ACOs must be willing to become accountable for total quality, cost, and overall care of these Medicare FFS beneficiaries. An ACO will not receive an assignment of those beneficiaries that choose not to receive care from ACO providers. Beneficiaries who choose to receive care from ACO providers, regardless of whether they are ''unmanageable'' or noncompliant with treatment recommendations may become part of the ACO's assigned population. Since patient-centeredness is an integral part of this program, we believe such beneficiaries represent an excellent opportunity for ACOs to create, implement, and improve upon patient-centered processes that improve patient engagement. We note that avoidance of such beneficiaries, as described in more detail in section II.H.3. of this final rule, will result in termination of an ACO's participation agreement. Similarly, in the interest of beneficiary engagement and transparency, we believe it is important to provide beneficiaries with an opportunity to decline data sharing. As discussed in greater detail in section II.B.4. of this final rule, a process for beneficiaries to decline data sharing provides an opportunity for ACOs to explain to patients how access to their personal health information will help the ACO improve the quality of its care. We believe that requiring an ACO executive who has the authority to bind the ACO to certify to the best of his or her knowledge, information, and belief that the ACO participants are willing to become accountable for, and to report to us on, the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO provides sufficient assurance that the ACO will be accountable for its assigned beneficiaries. By allowing ACOs to determine how they will satisfy this requirement, we will afford ACOs the flexibility needed to demonstrate their

commitment to beneficiary accountability in a manner which is most suited to their own ACO model.

Final Decision: We are finalizing our policy regarding certification of accountability for beneficiaries described in (76 FR 19544) as proposed without change (§ 425.100 and 425.204).

b. Agreement Requirement

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 * * *.'' For the first round of the Shared Savings Program, we proposed to limit participation agreements to a 3-year period. We sought comments on this proposal regarding the initial consideration of a longer agreement period.

If the ACO is approved for participation, we proposed that an authorized executive—specifically, an executive who has the ability to bind the ACO must certify to the best of his or her knowledge, information, and belief that its ACO participants and its ACO providers/suppliers agree to the requirements set forth in the agreement between the ACO and us, and sign a participation agreement and submit the signed agreement to us. We proposed that the participation agreement would also include an acknowledgment that all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other entities furnishing services related to ACO activities would require compliance with the ACO's obligations under the agreement. Additionally, we expressed our intention that all ACOs, ACO participants, and ACO providers/suppliers Shared Savings Program would be subject to the requirements of the agreement between the ACO and CMS and that all certifications submitted on behalf of the ACO in connection with the Shared Savings Program application, agreement, shared savings distribution or otherwise extend to all parties with obligations to which the particular certification applies.

An authorized executive of the ACO would sign the participation agreement after its approval for participation. Finally, we proposed that the ACO would be responsible for providing a copy of the agreement to its ACO participants and ACO providers/suppliers. We solicited comment on this proposal, including any additional measures or alternative means that we should consider to fulfill this requirement.

Comment: Commenters requested that CMS define the term authorized executive when stating that an authorized executive of the ACO must sign the participation agreement.

Response: As we stated in the proposed rule, an authorized executive is an executive of the ACO who has the ability to bind the ACO to comply with all of the requirements for participation in the Shared Savings Program.

Final Decision: We are finalizing this proposal regarding agreements as described previously under § 425.208 and § 425.210.

Further, as described in § 425.200, the ACO's agreement period will be for not less than 3 years, consistent with statute, although some agreement periods may be longer than 3 years.

c. Sufficient Number of Primary Care Providers and Beneficiaries

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 FFS beneficiaries assigned to the ACO * * *'' and that at a minimum, ''the ACO shall have at least 5,000 such beneficiaries assigned to it * * *.'' Physician patient panels can vary widely in the number of FFS Medicare beneficiaries served. In section II.E. of this final rule, we discuss our assignment methodology and how its use in the assignment of beneficiaries during the baseline years in order to establish a historical per capita cost benchmark against which the ACO's evaluation during each year of the agreement period would take place. In the proposed rule, we stated we believed it would be reasonable to assume that if by using this assignment algorithm the ACO demonstrates a sufficient number of beneficiaries to fulfill this eligibility requirement for purposes of establishing a benchmark, then the ACO would also demonstrate that it contains a sufficient number of primary care professionals to provide care to these beneficiaries. We stated we believed it was also reasonable to assume the ACO would continue to approximate this number of beneficiaries in each year of the agreement period. Thus, we proposed that for purposes of eligibility under section 1899(b)(2)(D) of the Act, an ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the 3-year benchmarking period using the ACO participant TINs exceeds the 5,000 threshold for each year. We solicited comment on this proposal as well as any additional guidance to consider for meeting these requirements.

We recognize that while an ACO could meet the requirements in section 1899(b)(2) of the Act when it applies to participate in the Shared Savings Program, circumstances may change during the course of the agreement period. We discussed the importance of maintaining at least 5,000 assigned beneficiaries with respect to both eligibility of the ACO to participate in the program and the statistical stability for purposes of calculating per capita expenditures and assessing quality performance. Therefore, we considered what action, if any, should be taken in the event the number of beneficiaries assigned to the ACO falls below 5,000 in a given performance year. Specifically, we considered whether an ACO's participation in the program should be terminated or its eligibility for shared savings be deferred if the number of beneficiaries drops below 5,000. We considered several options including immediate termination, termination following a CAP, scaling shared savings payments to reflect the population change, or taking no action against the ACO. After weighting all these options, we concluded that a reasonable compromise would balance the statutory requirements and program incentives, while still recognizing expected variations in an ACO's assigned population. Thus, if an ACO's assigned population falls below 5,000 during the course of the agreement period, we proposed to issue a warning and place the ACO on a corrective action plan (CAP). For the performance year for which we issued the warning to the ACO, we proposed that the ACO would remain eligible for shared savings. We further proposed termination of the ACO's participation agreement if the ACO failed to meet the eligibility criterion of having more than 5,000 beneficiaries by the completion of the next performance year. The ACO would not be eligible to share in savings for that year. We also reserved the right to review the status of the ACO while on the corrective action plan and terminate the agreement on the basis that the ACO no longer meets eligibility requirements. We requested comment on this proposal and on other potential options for addressing situations where the assigned beneficiary population falls below 5,000 during the course of an agreement period.

Comment: Commenters generally agreed that an ACO must have a strong primary care foundation with a sufficient number of providers to meet the needs of the population it serves. Additionally, commenters suggested

that there must be strong collaboration among multidisciplinary team members to ensure care coordination and patient centered care.

Some commenters recommended that ACOs should be required to demonstrate sufficiency in the number, type, and location of providers available to provide care to the beneficiaries. Other commenters noted that the proposed rule did not mention any requirement that the ACO demonstrate sufficiency in the number, type and location of all providers available to provide multi-disciplinary care to the beneficiaries.

Some commenters recommended that the minimum threshold of beneficiaries be increased to as high as 20,000 beneficiaries to reduce uncertainties in achieving program goals while other commenters believed that the 5,000 beneficiary threshold will preclude smaller and rural entities from participating in the Shared Savings Program as forfeiture of any shared savings and termination in the year following the corrective action plan would be too financially risky when the initial start up costs are taken into account.

One commenter suggested that rather than maintain a strict 5,000 beneficiary threshold requirement, we should provide leeway to ACOs to allow for a 10 percent variation from the beneficiary minimum threshold.

Response: Congress established the 5,000 beneficiary requirement under section 1899(b)(2)(D) of the Act. A minimum threshold is important with respect to both the eligibility of the ACO to participate in the program and to the statistical stability for purposes of calculating per capita expenditures and assessing quality performance as described in section II.D. of this final rule. However, the expanded assignment methodology discussed in section II.E. of this final rule should allow more beneficiaries to be assigned to those ACOs that might have initially been ''too close'' to the threshold, increasing the ability for smaller ACOs to participate. We do not believe this warrants an increase in the threshold number of assigned beneficiaries as that could prohibit the formation of ACOs in both smaller and rural health care markets, and possibly considered contrary to statutory intent. Additionally, the expanded assignment methodology discussed in section II.E. of this final rule should allow the assignment of more beneficiaries which should make the additional flexibility offered by allowing for a 10 percent variation in the assigned population unnecessary.

We do not believe that we should be prescriptive in setting any requirements for the number, type, and location of the providers/suppliers that are included as ACO participants. Unlike managed care models that lock in beneficiaries to a network of providers, beneficiaries assigned to an ACO may receive care from providers and suppliers both inside and outside the ACO. ACOs represent a new model for the care of FFS beneficiaries and for practitioners to focus on coordination of care efforts. During the initial implementation of the Shared Savings Program, we believe that potential ACOs should have the flexibility to create an organization and design their models in a manner they believe will achieve the three-part aim without instituting specific requirements.

Final Decision: We are finalizing our proposals without change (§ 425.110).

d. Identification and Required Reporting on Participating ACO Professionals

Section 1899(b)(2)(E) of the Act requires ACOs to ''provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements * * *, and the determination of payments for shared savings * * *.'' As discussed in this section of the final rule, we are defining an ACO operationally as a legal entity that is comprised of a group of ACO participants as defined in § 425.20.

Based on our experience, we recognized that the TIN level data alone would not be entirely sufficient for a number of purposes in the Shared Savings Program. In particular, National Provider Identifier (NPI) data would be useful to assess the quality of care furnished by an ACO. For example, NPI information would be necessary to determine the percentage of registered HITECH physicians and other practitioners in the ACO (discussed in section II.F. of this final rule). NPI data would also be helpful in our monitoring of ACO activities (which we discuss in section II.H. of this final rule). Therefore, we proposed to require that organizations applying to be an ACO must provide not only their TINs but also a list of associated NPIs for all ACO professionals, including a list that separately identifies physicians that provide primary care.

We proposed that the ACO maintain, update, and annually report to us the TINs of its ACO participants and the NPIs associated with the ACO providers/suppliers. We believe that requiring this information offers the level of transparency needed to implement the Shared Savings Program. We welcomed comments on our proposal to require reporting of TINs along with information about the NPIs associated with the ACO.

Additionally, as we discussed in the proposed rule, the first step in developing a method for identifying an ACO, ACO participants, and ACO providers/suppliers is to establish a clear operational method of identifying an ACO that correctly associates its health care professionals and providers with the ACO. The operational identification is critical for implementation of the program and for determining, for example, benchmarking, assignment of beneficiaries, and other functions. Section 1899(a)(1)(A) of the Act defines ACOs as ''groups of providers of services and suppliers'' who work together to manage and coordinate care for Medicare FFS beneficiaries. More specifically, the Act refers to group practice arrangements, networks of individual practices of ACO professionals, partnerships or joint venture arrangements between hospitals and ACO professionals, hospitals employing ACO professionals, or other combinations that the Secretary determines appropriate.

We proposed to identify an ACO operationally as a collection of Medicare enrolled TINs, defined as ACO participants. More specifically, we proposed an ACO would be identified operationally as a set of one or more ACO participants currently practicing as a ''group practice arrangement'' or in a ''network'' such as where ''hospitals are employing ACO professionals'' or where there are ''partnerships or joint ventures of hospitals and ACO professionals'' as stated under section 1899(b)(1)(A) through (E) of the Act. For example, Shared Savings Programs TIN would identify a single group practice that participates in the Shared Savings Program. The set of TINs of the practices would identify a network of independent practices that forms an ACO. We proposed to require that organizations applying to be an ACO provide their ACO participant Medicare enrolled TINs and NPIs. We can systematically link each TIN or NPI to an individual physician specialty code.

We also proposed that ACO participants on whom beneficiary assignment is based, would be exclusive to one ACO agreement in the Shared Savings Program. Under our proposal, this exclusivity would only apply to ACO participants who bill Medicare for the services rendered by primary care

physicians (defined as physicians with a designation of internal medicine, geriatric medicine, family practice and general practice, as discussed later in this final rule).

However, we acknowledged the importance of competition in the marketplace to improving quality of care, protecting access to care for Medicare beneficiaries, and preventing fraud and abuse. Therefore, under our proposal, ACO participants upon which beneficiary assignment was not dependent (for example, acute care hospitals, surgical and medical specialties, RHCs, and FQHCs) would be required to agree to participate in the Medicare ACO for the term of the agreement, but would not be restricted to participation in a single ACO.

Comment: Several commenters recommended that CMS maintain the list of TINs and NPIs. Additionally, some commenters recommended that CMS allow ACOs to verify any data reported in association with the ACO prior to these data being made public.

Response: Section 1899(b)(2)(E) of the Act requires ACOs to ''provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements * * *, and the determination of payments for shared savings * * *.'' As discussed previously, we will need both the TINs of all ACO participants and the NPIs associated with ACO providers/suppliers in order to assign beneficiaries to ACOs appropriately and accurately. Because section 1899(b)(2)(E) of the Act requires ACOs to provide us with the information we determine is necessary to support assignment, we believe it is consistent with this statutory requirement to require that ACOs maintain, update, and annually report to us those TINs and NPIs that are participants of their respective ACO. Since ACOs will be maintaining, updating, and annually reporting these TINs and NPIs to us, they will have ultimate review capabilities and it will not be necessary for us to provide them an additional opportunity to verify the names of ACO participants and ACO providers/suppliers before making this information available to the public. We note that, in order to ensure the accurate identification of any ACO, its participants, and its providers/suppliers, we may request additional information (for example, CMS Certification Numbers, mailing addresses, etc.) in the application process. We will identify any such additional information in the application materials.

Comment: One commenter stated that our assessment of billing practices was incorrect because ''beginning on May 23, 2008, all health care providers, including those enrolled in the Medicare and Medicaid program, are required by the NPI Final Rule published on January 23, 2004, to submit claims using their NPI'' but also notes that physicians participating in the Medicare program must enroll using their NPI and if they are billing through a group practice reassign their benefits to the group practice.

Response: It is true that individuals and group practices must enroll in the Medicare program under unique NPIs. It is also true that NPIs (whether for an individual practitioner or a group practice for reassigned benefits) must be included on bills to the Medicare program. However, bills to the Medicare program must also include the TIN of the billing practitioner or group practice. As we stated in the proposed rule, not all physicians and practitioners have Medicare enrolled TINs. In the case of individual practitioners, however, their SSN may be their TIN. While providers are required to have an NPI for identification and to include the NPI in billing, billing is always through a TIN, whether that is an EIN or a SSN. We successfully employed TINs in the PGP demonstration for purposes of identifying the participating organizations, and the rules cited by the commenters did not pose any obstacle to doing so. We believe that we can operationally proceed on the same basis under the Shared Savings Program.

Comment: Some commenters supported the proposal to use TINs as an organizing concept for ACOs. These commenters observed, for example, that this policy was consistent with the beginning of the PGP demonstration, under which the assignment of Medicare beneficiaries would start with the TIN of the organization providing the plurality of the visits with further assignment to a primary care provider. However, a number of other commenters requested that we reevaluate the proposal to employ TINs for identification of ACOs and assignment purposes. Some of these commenters suggested that the use of NPIs would recognize the realities of diverse systems, provide greater flexibility, and allow systems to designate those portions of the system which can most appropriately constitute an ACO. Other commenters similarly endorsed the use of NPIs as providing greater flexibility and more precision in identifying ACOs and assigning beneficiaries. One observed that using NPIs would also allow CMS and ACOs to track saving and quality improvements achieved by individual practitioners, as well as afford greater flexibility for systems to expand an ACO gradually to incorporate practitioners and components of the system.

Response: We are finalizing our proposal to define the ACO operationally by its Medicare enrolled ACO participants' TINs. Using TINs provides a direct link between the beneficiary and the practitioner(s) providing the services for purposes of beneficiary assignment. Using TINs also makes it possible for us to take advantage of infrastructure and methodologies already developed for group-level reporting and evaluation. We believe this option affords us the most flexibility and statistical stability for monitoring and evaluating quality and outcomes for the population of beneficiaries assigned to the ACO. In contrast, adopting NPIs would create much greater operational complexity because individual NPIs move much more frequently between different organizations and practices. TINs are much more stable, and thus provide much greater precision in identifying ACOs. Furthermore, identifying through TINs avoids the necessity of making the NPIs upon which assignment is based exclusive to one ACO, thus allowing these NPIs (although not TINs) to participate in more than one ACO.

Comment: Several commenters requested clarification about the use of TINs in identifying ACOs and assigning beneficiaries. Some inquired about the establishment of parameters of an ACO across a large health system with diverse and sometimes geographically remote components. Some of these commenters noted that large systems often employ a single TIN, so that the use of TINs for identification purposes would require inclusion of all the members of the system in a single ACO, even if these members are geographically remote from each other and otherwise diverse. One observed: ''Such remote entities may have a limited opportunity to participate in care coordination, and may in fact be better suited to participate in another more local ACO.'' A large clinic similarly observed that ''the use of TINs could pose a problem for large health systems.'' The owner of outpatient rehabilitation clinics in several States inquired how it would choose a single ACO in which to participate in order to serve the needs of patients in multiple States. Another asked whether it is permissible for some members of a

group practice to participate in the Shared Savings Program while others do not, adding their ''strong belief'' that participation in an ACO of some but not all providers in a group ''must be allowed.'' Another asked ''how CMS will account for the alignment of the beneficiary, signed up/enrolled with the PCP if the NP or PA saw the patient and billed using their individual NPI (which is linked to the ''PCP' physician's Tax ID), but the credit is not being assigned to the PCP physician because s/he isn't billing for the services. This could create a big gap and problem in the allocation process.'' Another commenter asked how the program would handle the situation in which a healthcare system has multiple TINs.

Response: We proposed to define an ACO operationally as a collection of Medicare enrolled TINs (that is, ACO participants). Therefore, in cases in which a healthcare system has multiple TINs, the collection of the system's TINs precisely identifies the ACO which consists of that health system. We understand the commenters' interest in the greater flexibility of, for example, including only parts of a large system with one TIN in an ACO. However, some level of exclusivity is necessary in order for the assignment process to function correctly, and especially to ensure the accurate assignment of beneficiaries to one and only one ACO. Use of TINs rather than NPIs provides the greatest degree of flexibility consistent with this requirement. Therefore, we are unable to allow, for example, a large health system with one TIN to include only parts of the system in an ACO. Systems that extend over several States can similarly choose more than one ACO for parts of their system only if they have multiple TINs. In order for a beneficiary to be assigned to an ACO in which his or her primary care physician is participating, the physician would have to bill for primary care services furnished to the beneficiary under a TIN included in that ACO.

Comment: Many commenters objected to the exclusivity of primary care physicians on the grounds that that such exclusivity could be disruptive of their current practice patterns, which may involve the assignment of patients to a number of ACOs. Some objected that the proposed lock in was unfair.

Another commenter complained that we did not sufficiently address the reasons for the lock in. Some commenters suggested methods to avoid the potential confusions that could occur in assigning beneficiary without our proposed lock in. For example, one commenter observed potential avoidance of this problem by creating incentives (for example, no deductibles and reduced co-insurance for primary care physician services) for patients to prospectively identify a primary care physician in an ACO. The commenter maintained that patients need to be accountable as well as the participating physicians and providers. Furthermore, the commenter contended that identification of a primary care physician does not have to limit patient choice in any way, but simply provides an alternative method for identifying the population of patients for which the ACO is responsible while getting more engaged patients to think about having a usual source of care. Alternatively, the commenter recommended that CMS should prospectively allow patients to choose their own Medicare ACO. This would relieve CMS from the proposed and flawed beneficiary attribution method that currently limits primary care physicians to participate in only one Medicare ACO.

Several other commenters opposed the lock in but suggested that, if we retain it, the final rule should—

- Permit primary care physicians to elect consideration as specialists without taking into account their evaluation and management services for the purpose of aligning beneficiaries with an ACO;
- Permit specialists to elect to be treated as primary care physicians whose evaluation and management services will be considered for beneficiary alignment; and
- Permit primary care physicians to participate in ACOs on an individual basis, rather than through their group practice entities or employers.

In either case, the final rule should encourage providers to work collaboratively to achieve savings and enhance care by allowing ACOs to arrange for medical services using contracted providers.

Another commenter requested that we revisit this requirement and provide additional flexibility so that primary care providers could join more than one ACO or switch ACOs on an annual basis. Commenters suggested alternative assignment strategies that would allow participation in more than one ACO such as default assignment to practitioners who are only in one ACO or having practitioners assign patients to a particular ACO based on patient needs. Some commenters also argued for adopting a policy of voluntary beneficiary enrollment in an ACO, arguing in part that this policy would allow us to abandon the proposal restricting primary care physicians to participation in one ACO, which we proposed to prevent uncertainty in the assignment process. Other commenters specifically requested that rural physicians and ambulance providers be able to participate in multiple ACOs.

Response: We regret that some of the language in the preamble about the exclusivity of ACO participants (defined by the Medicare-enrolled billing TIN) created unnecessary confusion about the proposal. The point of our proposal was that, for us to appropriately evaluate ACO performance, we must evaluate performance based on a patient population unique to the ACO. Therefore, some ACO participants, specifically those that bill for the primary care services on which we proposed to base assignment, would have to be exclusive to an ACO, for the purpose of Medicare beneficiary assignment, for the duration of an agreement period. In the absence of such exclusivity and in a situation where an ACO participant is associated with two or more ACOs, it would be unclear which ACO would receive an incentive payment for the participant's efforts on behalf of its assigned patient population. Exclusivity of the assignment-based ACO participant TIN ensures unique beneficiary assignment to a single ACO. However, exclusivity of an ACO participant TIN to one ACO is not necessarily the same as exclusivity of individual practitioners (ACO providers/suppliers) to one ACO. We did state somewhat imprecisely in the preamble to the proposed rule that ''ACO professionals within the respective TIN on which beneficiary assignment is based, will be exclusive to one ACO agreement in the Shared Savings Program. This exclusivity will only apply to the primary care physicians.'' This statement appears to be the basis of the concerns expressed by many commenters, and we understand the reasons for those concerns. However, we stated the policy (76 FR 19563) we intended to propose more precisely elsewhere in the preamble, when we stated that ''[t]his exclusivity will only apply to primary care physicians (defined as physicians with a designation of internal medicine, geriatric medicine, family practice and general practice, as discussed later in this final rule) by whom beneficiary assignment is established *when billing under ACO participant TINs.* (Emphasis added). Similarly, in the proposed regulations text at § 425.5(c), we stated that ''each ACO must report to CMS the TINs of the ACO participants comprising the ACO along with a list of associated NPIs, at the beginning of each performance year and at other such times as specified by CMS. For purposes

of the Shared Savings Program, each ACO participant TIN upon which beneficiary assignment is dependent is required to commit to a 3-year agreement with CMS and will be exclusive to one ACO. ACO participant TINs upon which beneficiary assignment is not dependent are required to commit to a 3 year agreement to the ACO, and cannot require the ACO participant to be exclusive to a single ACO.''

Thus, the exclusivity necessary for the assignment process to work accurately requires a commitment of each assignment-based ACO participant to a single ACO for purposes of serving Medicare beneficiaries. It does not necessarily require exclusivity of each primary care physician (ACO provider/supplier) whose services are the basis for such assignment. For example, exclusivity of an ACO participant leaves individual NPIs free to participate in multiple ACOs if they bill under several different TINs. Similarly, an individual NPI can move from one ACO to another during the agreement period, provided that he or she has not been billing under an individual TIN. A member of a group practice that is an ACO participant, where billing is conducted on the basis of the group's TIN, may move during the performance year from one group practice into another, or into solo practice, even if doing so involves moving from one ACO to another. This degree of flexibility is, in fact, one reason for our preference to use TINs to identify ACO participants over NPIs: adopting NPIs in place of TINs would result in the much stricter exclusivity rules for individual practitioners to which so many commenters objected, than the use of TINs to identify ACOs. This flexibility is limited, once again, only in cases where the ACO participant billing TIN and individual TIN are identical, as in the case of solo practitioners. Even in those cases, moreover, it was not our intent (and it is no part of the policy that we are adopting in this final rule) that an individual practitioner may not move from one practice to another. But while solo practitioners who have joined an ACO as an ACO participant and upon whom assignment is based may move during the agreement period, they may not participate in another ACO for purposes of the Shared Savings Program unless they will be billing under a different TIN in that ACO.

We are therefore finalizing our proposal that each ACO participant TIN is required to commit to an agreement with us. In addition, each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one ACO for purposes of the Shared Savings Program. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to a single ACO for purposes for the Shared Savings Program. As we discuss in section E found later in this final rule we are also providing for consideration of the primary care services provided by specialist physicians, PAs, and NPs in the assignment process subsequent to the identification of the ''triggering'' physician primary care services. We are therefore also extending our exclusivity policy to these ACO participants. That is, the TINs under which the services of specialists, PAs, and NPs are included in the assignment process would have to be exclusive to one ACO for purposes of the Shared Savings Program. (We emphasize that we are establishing this policy for purposes of Shared Savings Program ACOs only: Commercial ACOs may or may not wish to adopt a similar policy for their purposes.)

Comment: One commenter supported our use of primary care physicians for alignment and urged us to retain the policy of non-exclusivity for specialists in the final rule: ''CMS's use of primary care physicians to align beneficiaries with an ACO is an important design element and we urge the agency to retain this provision in the final rule. As constructed, an ACO participant upon which beneficiary assignment is not dependent must not be required to be exclusive to an ACO (§ 425.5(c)(3)). In the newly proposed Pioneer ACO regulation however, beneficiary assignment could be made on the basis of several categories of specialist physicians. Extending this Pioneer attribution scheme to the proposed Medicare Shared Savings/ACO program could result in decreased availability of specialist physicians and/or a reluctance of non-ACO providers to refer to those specialists who are concerned that patients will be diverted to other ACO providers. We urge CMS to maintain the current rules aligning beneficiaries solely on the basis of their use of primary care physicians.''

Response: We appreciate the comment. However, in the light of our decision to employ a step-wise assignment process (as discussed in section II.E. of this final rule), this final exclusivity policy will also apply to ACO participants upon which assignment is based in either the first or second steps of the assignment process. As a result, this exclusivity will apply to ACO participants under which both primary care physicians and specialists bill for primary care services considered in the assignment process. However, we emphasize again that individual provider NPIs are not exclusive to one ACO, only the ACO participant TINs under which providers bill for services that are included in the assignment of beneficiaries. When providers whose services are the basis of assignment bill under two or more TINs, each TIN would be exclusive to only one ACO, assuming they have both joined as participants, but the provider (primary care physician or specialist) would not be exclusive to one ACO.

Comment: Many commenters objected to our proposal that FQHCs and RHCs could not form independent ACOs, but only participate in ACOs that included other eligible entities (for example, hospitals, and physician group practices). However, one commenter welcomed the opportunity for FQHCs to participate in multiple ACOs.

Response: As we discuss in section II.E. of this final rule, we are revising our proposed policy to allow FQHCs and RHCs to form independent ACOs. We have also revised our proposed assignment methodology in order to permit claims for primary care services submitted by FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC or RHC (whether as an independent ACO or in conjunction with other eligible entities). As a consequence of this revised policy, the exclusivity of the ACO participants upon which beneficiary assignment is dependent also extends to the TINs of FQHCs and RHCs upon which beneficiary assignment will be dependent under the new policies discussed in section II.E. of this final rule.

Final Decision: We are finalizing our proposals regarding operational definition of an ACO as a collection of Medicare-enrolled TINs, the obligation of the ACO to identify their ACO participant TINs and NPIs on the application, the obligation of the ACO to update the list, and the required exclusivity of ACO participants upon whom assignment is based without change under sections 425.20, 425.204(5), 425.302(d), 425.306, respectively. We clarify that ACO participants upon which beneficiary assignment is not dependent are not required to be exclusive to a single Medicare Shared Savings Program ACO. This final exclusivity policy extends to the ACO participant TINs of FQHCs, RHCs and ACO participants that include NP, PAs, and specialists upon which beneficiary assignment will be dependent under the revised assignment methodology discussed in section II.E. of this final rule.

2. Eligible Participants

Section 1899(b) of the Act establishes eligibility requirements for ACOs participating in the Shared Savings Program. Section 1899(b)(1) of the Act allows several designated groups of providers of services and suppliers to participate as an ACO under this program, ''as determined appropriate by the Secretary,'' and under the condition that they have ''established a mechanism for shared governance.'' The statute lists the following groups of providers of services and suppliers as eligible to participate as an ACO:

- ACO professionals in group practice arrangements.
- Networks of individual practices of ACO professionals.
- Partnerships or joint venture arrangements between hospitals and ACO professionals.
- Hospitals employing ACO professionals.
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Section 1899(h)(1) of the Act defines an ''ACO professional'' as a physician (as defined in section 1861(r)(1) of the Act, which refers to a doctor of medicine or osteopathy), or a practitioner (as defined in section 1842(b)(18)(C)(i) of the Act, which includes physician assistants, nurse practitioners, and clinical nurse specialists). Section 1899(h)(2) of the Act also 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, thus limiting the definition to include only acute care hospitals paid under the hospital inpatient prospective payment system (IPPS). Other providers of services and suppliers that play a critical role in the nation's health care delivery system, such as federally qualified health centers (FQHCs), rural health centers (RHCs), skilled nursing facilities (SNFs), nursing homes, long-term care hospitals (LTCHs), critical access hospitals (CAHs), nurse midwives, chiropractors, and pharmacists, among others, are not specifically designated as eligible participants in the Shared Savings Program under section 1899(b)(1) of the Act. Furthermore, while the statute enumerates certain kinds of provider and supplier groups that are eligible to participate in this program, it also provides the Secretary with discretion to tailor eligibility in a way that narrows or expands the statutory list of eligible ACO participants. Therefore, we explored several options: (1) Permit participation in the program by only those ACO participants that are specifically identified in the statute; (2) restrict eligibility to those ACO participants that would most effectively advance the goals of the program; or (3) employ the discretion provided to the Secretary under section 1899(b)(1)(E) of the Act to expand the list of eligible groups to include other types of Medicare-enrolled providers and suppliers identified in the Act. After evaluating the three alternatives, we decided to propose the third option.

Since the statute requires that beneficiary assignment be determined on the basis of utilization of primary care services provided by ACO professionals that are physicians, we considered whether it would be feasible for CAHs, FQHCs, and RHCs to form an ACO or whether it would be necessary for these entities to join with one of the four groups specified in section 1899(b)(1)(A)–(D) of the Act in order to meet statutory criteria. We especially considered the circumstances of CAHs, FQHCs, and RHCs because these entities play a critical role in the nation's health care delivery system, serving as safety net providers of primary care and other health care and social services. At the same time, we noted that the specific payment methodologies, claims billing systems, and data reporting requirements that apply to these entities posed some challenges in relation to their independent participation in the Shared Savings Program. In order for an entity to be able to form an ACO, it is necessary that we obtain sufficient data in order to carry out the necessary functions of the program, including assignment of beneficiaries, establishment and updating of benchmarks, and determination of shared savings, if any. As we discuss in section II.E. of this final rule, section 1899(c) of the Act requires the assignment of beneficiaries to an ACO based on their utilization of primary care services furnished by a physician. Thus, as required by the statute, the assignment methodology requires data that identify the precise services rendered (that is, primary care HCPCS codes), type of practitioner providing the service (that is, a MD/DO as opposed to NP, PA, or clinical nurse specialist), and the physician specialty in order to be able to assign beneficiaries to ACOs.

We proposed that because of the absence of certain data elements required for assignment of beneficiaries, it would not be possible for FQHCs and RHCs to participate in the Shared Savings Program by forming their own ACOs. We stated that as the Shared Savings Program developed, we would continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and in light of any such developments, we would consider whether it would be possible at some future date for Medicare beneficiaries to be assigned to an ACO on the basis of services furnished by an FQHC or RHC, thereby allowing these entities to have their Medicare beneficiaries included in the ACO's assigned population.

In the proposed rule, we further considered whether CAHs could participate in the Shared Savings Program by forming an independent ACO. We noted the situation is somewhat more complicated with regard to CAHs because section 1834(g) of the Act provides for two payment methods for outpatient CAH services. We described the payment methods in detail and determined that current Medicare payment and billing policies could generally support the formation of an ACO by a CAH billing under section 1834(g)(2) (referred to as method II).

In summary, we proposed that the four groups specifically identified in section 1899(b)(1)(A)–(D) of the Act (various combinations of physicians, nurse practitioners, physician assistants, clinical nurse specialists, and acute care hospitals), and CAHs billing under method II, would have the opportunity, after meeting the other eligibility requirements, to form ACOs independently. In addition, the four statutorily identified groups, as well as CAHs billing under method II, could establish an ACO with broader collaborations by including additional ACO participants that are Medicare enrolled entities such as FQHCs and RHCs and other Medicare-enrolled providers and suppliers not originally included in the statutory definition of eligible entities.

We indicated in the proposed rule that we would consider whether it would be appropriate to expand the list of entities eligible to participate in the Shared Savings Program, either in the final rule or in future rulemaking, if we determined that it was feasible and consistent with the requirements of the program for more entities to participate as ACOs independently. In the interim, and until such time as FQHCs and RHCs would be eligible to form ACOs or have their patients assigned to an ACO, we proposed to provide an incentive for ACOs to include RHCs and FQHCs as ACO participants, by allowing ACOs that include such entities to receive a higher percentage of any shared savings under the program. We discuss our final policies regarding the determination of shared savings under the program in section II.G. of this final rule.

Comment: A large number of commenters requested an expansion of those entities eligible to participate in the Shared Savings Program. The commenters requested that entities such as, but not limited to, integrated delivery systems, emergency medical technicians (EMTs), paramedics, health plans, Medicare Advantage (MA) plans, Medicaid Managed Care Organizations, AEMTs, community based hospitals, DME Suppliers, home health agencies (HHAs), long-term care (LTC) facilities, in-patient rehabilitation facilities, hospice facilities, patient-centered medical homes, RHCs, FQHCs, and Method I CAHs be included as eligible entities. We received one comment inquiring whether non-PECOS (Provider Enrollment, Chain, and Ownership System) enrolled providers can participate as ACO providers/suppliers. PECOs is a directory containing the names, addresses, phone numbers, and specialties of physicians enrolled in Medicare. Other comments suggested that we establish ESRD and cancer care specific ACOs. We received a few comments in support of limiting those entities eligible to participate in the program. These comments suggested that implementation of the Shared Savings Program will demand significant changes to health care delivery, data sharing, and data integration among providers and disparate groups. Providing clear guidance on who can participate reduces confusion and uncertainty within the provider and hospital community.

Response: We agree that limiting eligibility could potentially reduce confusion but also agree that the inclusion of some additional entities as eligible to independently participate in the program could significantly increase the opportunity for success. Although the entities referenced in the comment, with the exception of CAHs billing under method II, RHCs and FQHCs, are not able to independently form ACOs, these entities are not prohibited from participating in the Shared Savings Program so long as they join as an ACO participant in an ACO containing one or more of the organizations that are eligible to form an ACO independently and upon which assignment could be made consistent with the statute and the assignment methodology discussed in section II.E. of this final rule. Thus, although we do not see the need to design distinct ESRD or cancer specific ACOs, neither of these providers types are in any manner excluded from participation in an ACO. This allows for the four groups specifically identified in section 1899(b)(1)(A) through (D) of the Act, and CAHs billing under method II, RHCs, and FQHCs to form ACOs independently. In addition, the four statutorily identified groups, as well as CAHs billing under method II, RHCs, and FQHCs could establish an ACO with broader collaborations by including additional Medicare-enrolled entities defined in the Act as ACO participants. This will afford ACOs the flexibility to include all types of providers and suppliers as ACO participants, as long as the ACO can satisfy the required eligibility standards. Finally, enrollment in the PECOs system, at this time, is not a condition of eligibility to participate in the Shared Savings Program.

Comment: Many commenters, including MedPAC and commenters representing rural health advocates and a wide range of beneficiary and provider groups, raised concerns about the proposal which would preclude FQHCs and RHCs from forming independent ACOs. The commenters raised this issue in reference to eligibility, beneficiary assignment, and benchmarking issues. There were also several comments that agreed with the additional sharing rates for ACOs that include FQHCs and RHCs.

Commenters generally supported eligibility approaches that would allow FQHCs/RHCs to join ACOs formed by other entities. Some commenters also generally supported our proposal that FQHCs/RHCs would not be required to be exclusive to a single ACO. Although commenters were generally appreciative of the proposal to provide a higher sharing rate for ACOs that include FQHCs and RHCs, some commenters believed this approach was flawed, too weak to be effective, and could undercut the objectives of the Shared Savings Program. Most commenters expressed general concerns that the CMS interpretation of the statute was incorrect and that the statute allows the agency to promulgate policies that will allow for full participation of FQHCs in the Shared Savings Program. Some commenters focused their detailed comments on FQHCs, but the concerns/issues they raised were generally similar to those commenters that also addressed RHCs.

Several commenters stated that CMS' conclusions are flawed and that the law allows the agency to promulgate policies that will allow for full FQHC participation in the Shared Savings Program. They believe that ''a system that does not allow for meaningful FQHC involvement undercuts the Congressional intent in establishing the ACO/Shared Savings Program and the broader goal of assuring quality cost efficient health care services to Medicare beneficiaries.'' They expressed fear that other payers such as Medicaid, CHIP and private health insurers will follow Medicare's approach and policies in developing their own ACO rules, leading to disparities in care. Another commenter suggested our proposal would prevent or limit dually eligible patients from receiving integrated care at FQHCs in light of State Medicaid efforts to create ACOs and our definition of ''at risk'' beneficiaries.

Other commenters argued that RHCs represent a particularly compelling case for ACO formation inclusion. They believe that the promise of better integrated outpatient care for rural Medicare beneficiaries must begin with RHCs. These commenters believe that the exclusion of RHCs from those eligible to form an ACO independently would only serve to exclude rural providers and the populations they serve from forming efficiency enhancing ACOs that might serve to counterbalance the inpatient service-favoring skew that they believe has developed out of many rural preferential payment provisions.

Response: In this final rule we are addressing the specific comments regarding beneficiary assignment and the establishment of benchmarks for ACOs that include FQHCs and/or RHCs in sections II.E. and II.G. (Assignment and Benchmark) of this final rule while general comments regarding the eligibility of FQHCs and RHCs to form ACOs independently are addressed here. In the proposed rule, we proposed to use discretion afforded by the statute under section 1899(b)(1)(E) to allow participation of any Medicare-enrolled provider/supplier as an ACO participant. Thus, entities such as FQHCs and RHCs were eligible to participate in the program under our original proposal. However, we agree that it is highly desirable to allow for FQHCs and RHCs to participate independently and to determine a way to include their beneficiaries in assignment. In order for this to be possible, in this final rule we are making modifications to the proposed assignment process to recognize the different payment methodologies and claims data that are used by FQHCs and RHCs as compared to the payment methodologies and claims data that are available for physician offices/clinics that are paid under the physician fee schedule. The discussion about assignment and benchmarking process is in sections II.E. (Assignment) and II.G. (Benchmarking) of this final rule. As a result, under the policies

established in this final rule, FQHCs and RHCs will be eligible to form ACOs and may also be ACO participants in ACOs formed by other entities. Additionally, Medicare enrolled entities may join independent FQHCs, RHCs, and method II billing CAH ACOs.

Comment: Some commenters supported our proposal to allow CAHs billing under method II to form ACOs. A few commenters also recommended allowing CAHs billing under method I to form independent ACOs by supplementing their normal billing information with any additional information needed to assign beneficiaries. For example, a commenter indicated that because most rural facilities act as de facto sole providers for their communities, CAHs and SCH's should be able to claim all beneficiaries in their primary catchment area. The commenter suggested doing so by having the rural providers submit the 75th percentile zip codes from their patient demographic data. These zip codes could then be compared to the Medicare beneficiary claims data, and if the claims data also show that the beneficiaries in those zip codes receive >50 percent of their primary care services within the zip codes of the rural ACO, then all of the beneficiaries in those zip codes could be assigned to the rural ACO.

Response: We do not agree with allowing CAHs billing under method I to independently form ACOs by simply claiming all beneficiaries in their primary catchment area. We do not believe that this would be consistent with the statutory requirement for assignment based on beneficiary utilization of primary care services furnished by a physician. Although we do not believe it would be appropriate for a CAH billing under method I to independently form an ACO, we would emphasize that we would encourage CAHs billing under method I to participate in the Shared Savings Program by establishing partnerships or joint venture arrangements with ACO professionals, just like other hospitals.

Comment: Some commenters suggested using CMS's demonstration authority to include FQHCs and RHCs in the Shared Savings Program or another Shared Savings Program. Others recommended that CMS should continue to work with providers and patients practicing and living in rural underserved areas to develop ACO models specifically designed to meet the unique healthcare delivery challenges facing rural underserved areas.

Response: We appreciate the comments suggesting the development of ACO models to address the special needs of rural areas and have forwarded them to our colleagues in the Innovation Center. We will consider any additional demonstrations focused on ACOs as part of the regular process for establishing CMS demonstrations. We note, however, that as discussed previously, under the policies adopted in this final rule, FQHCs and RHCs will be eligible to form an ACO independently or to participate in an ACO formed by other eligible entities.

Comment: A few commenters suggested that CMS should refine its strategies to facilitate development of practitioner-driven, rather than hospital-driven ACO's. Comments further suggested that at the very least, waiver authority should be established to enable the agency to waive hospital-oriented requirements for ACOs that consist solely of group practices.

Response: There is no requirement that an ACO include a hospital. Similarly, we have not established any ''hospital-oriented'' requirements. We have intentionally provided ACOs the flexibility to establish their organizations in such a manner that will most effectively define their preferred ACO model.

Final Decision: We are finalizing our proposals for identifying groups of providers of services and suppliers that may join to form an ACO under § 425.102. Specifically, the entities identified in section 1899(b)(1)(A) through (D) of the Act will be able to form ACOs, provided they meet all other eligibility requirements. Additionally, CAHs billing under method II, FQHCs, and RHCs may also form independent ACOs if they meet the eligibility requirements specified in this final rule. In addition, any Medicare enrolled entities not specified in the statutory definition of eligible entities in section 1899(b)(1)(A)–(D) of the Act can participate in the Shared Savings Program as ACO participants by joining an ACO containing one or more of the organizations eligible to form an ACO. Additionally, in response to comments and after further consideration of the available information, we have established a process by which primary care services furnished by FQHCs and RHCs will be included in the assignment process, as discussed in section II.E. of this final rule. As a result, FQHCs and RHCs will also be able to form ACOs independently, provided they meet all other eligibility requirements.

3. Legal Structure and Governance

Section 1899(b)(2)(C) of the Act requires an ACO to ''have a formal legal structure that would allow the organization to receive and distribute payments for shared savings'' to ''participating providers of services and suppliers.'' As previously noted, section 1899(b)(1) of the Act also requires ACO participants to have a ''mechanism for shared governance'' in order to be eligible to participate in the program. Operationally, an ACO's legal structure must provide both the basis for its shared governance as well as the mechanism for it to receive and distribute shared savings payments to ACO participants and providers/suppliers.

a. Legal Entity

In order to implement the statutory requirements that ACOs have a shared governance mechanism and a formal legal structure for receiving and distributing shared payments, we proposed that an ACO be an organization that is recognized and authorized to conduct its business under applicable State law and is capable of—(1) receiving and distributing shared savings; (2) repaying shared losses, if applicable; (3) establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and (4) performing the other ACO functions identified in the statute. We explained that it is necessary for each ACO to be constituted as a legal entity appropriately recognized and authorized to conduct its business under applicable State law and that it must have a TIN. However, we did not propose to require ACO enrollment in the Medicare program.

We did not propose that existing legal entities form a separate new entity for the purpose of participating in the Shared Savings Program. We stated that if the existing legal entity met the eligibility requirements to be an ACO, it may operate as an ACO in the Shared Savings Program. However, we proposed that if an entity, such as a hospital employing ACO professionals would like to include as ACO participants other providers/suppliers who are not already part of its existing legal structure, an ACO would have to establish a separate legal entity in order to provide all ACO participants a mechanism for shared governance.

We also proposed that each ACO certify that it is recognized as a legal entity under State law and authorized by the State to conduct its business. In addition, an ACO with operations in multiple States would have to certify that it is recognized as a legal entity in the State in which it was established

and that it is authorized to conduct business in each State in which it operates.

We solicited comment on our proposals regarding the required legal structure and other suitable requirements that we should consider adding in the final rule or through subsequent rulemaking. We also requested comment on whether requirements for the creation of a separate entity would create disincentives for the formation of ACOs and whether there were alternative approaches that could be used to achieve the aims of shared governance and decision making and provide the ability to receive and distribute payments for shared savings.

Comment: Many commenters opposed requiring ACOs formed among multiple ACO participants to form a separate legal entity, because it was costly, inefficient, and wasteful to do so (especially for small and medium-sized physician practices). These commenters also contend that forming a separate entity places such ACOs at a competitive disadvantage relative to integrated delivery systems (for example single-entity ACOs), it will likely have a chilling effect on the willingness of such providers and suppliers to participate in the program, and it disadvantages hospitals in States with a prohibition on the corporate practice of medicine.

Several commenters supported allowing multiple participant ACOs to form an entity by contract and not require a separate new entity. These commenters recommended that we permit ACOs comprised of multiple ACO participants to designate one of those ACO participants to function as the ''ACO'' for purposes of participation in the program, provided that such entity meets the criteria required of an ACO under the final rule. Another commenter suggested letting a division of an existing corporation serve as the legal entity for an ACO. Specifically, this comment noted that license-exempt, medical foundation clinics in California are often formed as either a division of a nonprofit corporation that owns and operates a hospital or have as their sole corporate member a nonprofit hospital, such as a nonprofit, license-exempt, medical foundation clinic. One commenter suggested that ACOs that have outcome-based contracts with private payers should have flexibility in forming their legal entities.

Many commenters supported the proposal not to require creation of a new distinct legal entity if one is already in place that meets the proposed criteria. Commenters stated that such a requirement is unnecessary to meet the objectives of the Shared Savings Program. Some commenters suggested existing organizations should not be forced to create whole new bureaucracies just to add a few participants to form an ACO.

Response: We continue to support our proposal that each ACO certify that it is recognized as a legal entity under State law. An ACO formed among two or more otherwise independent ACO participants (such as between a hospital and two physician group practices) will be required to establish a separate legal entity and to obtain a TIN. Although some comments opposed this requirement as burdensome, we continue to believe it is essential to protect against fraud and abuse and ensure that the ACO is accountable for its responsibilities under the Shared Savings Program by enabling us to audit and assess ACO performance. In addition, to the extent an ACO becomes liable for shared losses, we believe it is essential to be able to collect such monies from the ACO and its ACO participants.

For existing legal entities that otherwise meet the eligibility requirements, we agree with commenters that requiring the creation of a new separate legal entity would be inefficient. Existing legal entities which are eligible to be ACOs are permitted to continue to use their existing legal structure as long as they meet other eligibility and governance requirements explained in this final rule. However, as we proposed, if an existing legal entity adds ACO participants that will remain independent legal entities (such as through a joint venture among hospitals or group practices), it would have to create a new legal entity to do so. As discussed later in this section, we believe that creation of a new legal entity would be important to allow the newly added ACO participants to have a meaningful voice on the ACO's governing body. A separate legal entity, with such a governing body, is therefore essential to accomplish this policy objective.

Although we recognize that it may be possible for ACOs to establish outcome-based contracts that reinforce some of the policy objectives discussed in the proposed rule, we believe that the proposed legal structure requirement is necessary to protect against fraud and abuse and ensure the goals of the Shared Savings Program, and does not impose too large a burden, especially in light of the flexible governance structure discussed later in this section.

Comment: Several commenters suggested we address the interplay between Federal and State law governing ACO formation and operation. For example, commenters suggested we clarify whether the proposed legal entity requirements include requiring an ACO to obtain a certificate of authority if so required under State law. One commenter suggested that we clarify whether we are requiring that an ACO be recognized as an ACO under State law or whether we are requiring that the ACO be recognized to conduct business as a partnership, corporation, etc. under State law.

Other commenters suggested that we preempt State law or regulation of ACOs that limit the number of ACOs in a State. By contrast, another comment suggested that the Affordable Care Act did not preempt or otherwise supersede State laws prohibiting the corporate practice of medicine or otherwise alter the choice of legal entities available to ACOs for formation in particular States. In addition, some commenters recommended that we require that if an ACO assumes insurance risk, it should meet all the consumer protection, market conduct, accreditation, solvency, and other requirements consistent with State laws.

One commenter suggested that we require ACOs that operate in more than one State to attest that they operate under each State's rules rather than a blend of multiple States' rules for all business and other operational functions (including health information management, release of information, privacy/confidentiality, data quality, etc.). Some commenters suggested that the proposed definition of ''ACO'' would exclude entities organized pursuant to Federal and tribal law, and recommended that we also allow ACOs to be organized under Federal or tribal law as well.

Response: We continue to believe that an ACO should be recognized as a legal entity under State law and authorized by the State to conduct its business. We intended this requirement to ensure the ACO would be licensed to do business in the State consistent with all applicable State law requirements. Consequently, we are finalizing our proposal that an ACO that participates in the Shared Savings Program meet State law requirements to operate in that State. We are not requiring an ACO be licensed as an ACO under State law unless, however, State law requires such licensure.

We disagree with the commenters that participating in the Shared Savings Program ultimately involves insurance risk. ACO participants will continue to receive FFS payments for all services

furnished to assigned beneficiaries. It is only shared savings payments (and shared losses in the two-sided model) that will be contingent upon ACO performance. As a result, we believe that we will continue to bear the insurance risk associated with the care furnished to Medicare beneficiaries, but ACOs desiring to participate in Track 2 should consult their State laws.

To clarify, we are not preempting any State laws or State law requirements in this final rule. To the extent that State law affects an ACO's operations, we expect the ACO to comply with those requirements as an entity authorized to conduct business in the State. We do not believe it is necessary to make ACOs attest to do what they otherwise would be required to do under State law.

We agree with commenters that we do not want to exclude ACOs that are licensed under Federal or tribal law. Accordingly, we are modifying our original proposal to clarify that entities organized pursuant to Federal and tribal law will also be allowed to participate in the Shared Savings Program, as long as the entity is able to meet the participation requirements as outlined in this final rule.

Final Decision: We are finalizing our proposal that an ACO must be a legal entity for purposes of all program functions identified in this final rule. We are also finalizing commenters' suggestion that ACOs licensed under Federal or tribal law are eligible to participate in the Shared Savings Program. In addition, an ACO formed among multiple ACO participants must provide evidence in its application that it is a legal entity separate from any of its ACO participants. (§ 425.104)

b. Distribution of Shared Savings

As discussed previously, an ACO must be a legal entity appropriately recognized and authorized to conduct its business under State, Federal, or tribal law, and must be identified by a TIN. In the proposed rule we proposed to make any shared savings payments directly to the ACO as identified by its TIN, we noted that unlike the ACO participants and the ACO providers/suppliers that form the ACO, the legal entity that is the ACO may or may not be enrolled in the Medicare program. We acknowledged the potential for this proposal to raise program integrity concerns, because allowing shared savings payments to be made directly to a non-Medicare-enrolled entity would likely impede the program's ability to recoup overpayments as there would be no regular payments that could be offset. This is part of the rationale for requiring safeguards for assuring ACO repayment of shared losses described in section II.G. of this final rule. We solicited comment on our proposal to make shared savings payments directly to the ACO, as identified by its TIN. In addition, we solicited comment on our proposal to make shared savings payments to a non-Medicare-enrolled entity.

We proposed to require ACOs to provide a description in their application of the criteria they plan to employ for distributing shared savings among ACO participants and ACO providers/suppliers, how any shared savings will be used to align with the three-part aim. As we stated in the proposed rule, we believe this requirement would achieve the most appropriate balance among objectives for encouraging participation, innovation, and achievement of an incentive payment while still focusing on the three-part aim.

Comment: Several commenters recommended that CMS explicitly state that the ACO is required to demonstrate that ACO participants will be able to share in savings and that CMS outline exactly how the savings will be distributed while other commenters suggested that CMS work with the provider community to develop principles that ACOs should follow to ensure fair and equitable distribution of shared savings. Other commenters suggested that a requirement be established that some pre-determined portion of any shared savings be directed to improving patient care unless there is little room for improvement for ACOs in the final quality measures. A few commenters requested that standards be established regarding the length of time (ranging from 15 days to 90 days) an ACO has to actually share any savings generated with its respective providers. Finally, a commenter expressed concern that when partnering with a hospital-based system, primary care providers would not be rewarded for the significantly increased work that will be required on their part in order for an ACO to be successful. Instead this money would be used by the hospital system to replace lost revenue on the hospital side.

Response: We will make any shared savings payments directly to the ACO as identified by its TIN. As explained in the proposed rule, the statute does not specify how shared savings must be distributed, only that the ACO be a legal entity so that the ACO can accept and distribute shared savings. We do not believe we have the legal authority to dictate how shared savings are distributed, however, we believe it would be consistent with the purpose and intent of the statute to require the ACO to indicate as part of its application how it plans to use potential shared savings to meet the goals of the program. Consistent with the discussion found later in this final rule regarding the shared governance of an ACO, we anticipate that ACO participants would negotiate and determine among themselves how to equitably distribute shared savings or use the shared savings to meet the goals of the program.

Final Decision: We will finalize our proposals under § 425.204(d) without change.

c. Governance

Section 1899(b)(1) of the Act requires that an ACO have a ''mechanism for shared governance'' and section 1899(b)(2)(F) of the Act requires that an ''ACO shall have in place a leadership and management structure that includes clinical and administrative systems.'' However, the statute does not specify the elements that this shared governance mechanism or the accompanying leadership and management structures must possess. We proposed that such a governance mechanism should allow for appropriate proportionate control for ACO participants, giving each ACO participant a voice in the ACO's decision making process, and be sufficient to meet the statutory requirements regarding clinical and administrative systems.

We proposed that an ACO also must establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO. The governing body may be a board of directors, board of managers, or any other governing body that provides a mechanism for shared governance and decision-making for all ACO participants, and that has the authority to execute the statutory functions of an ACO, including for example, to ''define processes to promote evidenced-based medicine and patient engagement, report on quality and cost measures, and coordinate care.'' We proposed that this body must be separate and unique to the ACO when the ACO participants are not already represented by an existing legal entity appropriately recognized and authorized to conduct its business under applicable State law. In those instances where the ACO is an existing legal entity that has a pre-existing board of directors or other governing body, we proposed that the ACO would not need to form a separate governing body. In this case, the existing entity's governing body would be the governing body of the ACO, and the ACO would be required to provide in its application

evidence that its pre-existing board of directors or other governing body, meets all other criteria required for ACO governing bodies. We also proposed that the ACO have a conflicts of interest policy that applies to members of the governing body. The conflicts of interest policy must require members of the governing body to disclose relevant financial interests. Further, the policy must provide a procedure for the ACO to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise. Such a policy also must address remedial action for members of the governing body that fail to comply with the policy.

We requested comment on whether these requirements for the creation of a governing body as a mechanism for shared governance would create disincentives for the formation of ACOs and whether there were alternative requirements that could be used to achieve the aims of shared governance and decision making. We also acknowledged that allowing existing entities to be ACOs would complicate our monitoring and auditing of these ACOs, and sought comment on this issue.

Comment: Although most comments supported the principle of ACO shared governance, many commenters opposed the separate governing body requirement. Some commenters stated that we exceeded our authority by imposing a separate governing body requirement. Other commenters suggested that the separate governing body requirement would discourage organizations from participating in the Shared Savings Program and increase their costs to do so. Commenters explained that existing entities already have relationships with commercial payers and it would not make sense for them to maintain multiple boards, because it is costly and organizationally complex to do so.

Many commenters urged us to provide flexibility so that ACOs could use their current governance process, as long as they can demonstrate how they will achieve shared governance on care delivery policies. Some commenters explained that hospitals and other large physician groups have governing bodies designed specifically for quality and outcome reviews and oversight for clinical integration and performance appraisal, training and discipline. Commenters suggested that ACOs can be effectively governed by an operating committee within their existing governance and management structure, as is a hospital medical staff governed semi-autonomously within a hospital's governance structure. Commenters also suggested that ACOs should be permitted to access existing assets and systems, such as advisory boards, so long as the ACO management committee exercises sufficient control over these processes with respect to ACO activities to generate ACO desired outcomes. Other commenters had specific concerns about how the separate entity requirement would apply to their current or planned organizational structure. One commenter, an integrated, State-wide health system, suggested that we permit it to operate as a State wide/multi-State ACO with various regional/local ACOs as its ACO participants. In this structure, the corporate organization would handle the claims processing, reporting, and distribution of savings and the financial backing for potential loss for the regional ACO healthcare operational units. The regional ACOs would have their own board and each regional ACO would be represented on the State-wide/multi-State board. This commenter claimed that this type of structure would take advantage of the cost savings that result from economies of scale for administrative and other functions, but would keep health care delivery local. Another commenter suggested allowing an ACO governing body's authority to be delegated from an existing governing body that possesses broad reserved powers.

One commenter suggested we clarify the responsibilities of the board as distinct from those of management. In this commenter's view, governing board's role should be one of oversight and strategic direction, holding management accountable to meeting goals of ACO. Another commenter suggested that the governance structure be organized more like a scientific advisory board that will analyze the results of the particular ACO's methodology for treating its patients.

Response: Our proposal to require an ACO to have a separate governing body unless it is an existing legal entity that has a pre-existing governing body is consistent with the proposed and final requirements regarding legal entity requirements discussed previously. Thus, we disagree with the commenters that suggested that such a requirement would discourage participation in the Shared Savings Program or disrupt existing relationships with commercial payers.

Moreover, for ACOs formed among otherwise independent ACO participants, we will finalize our proposal that these ACOs create an identifiable governing body. This requirement is consistent with our final rule that requires such ACOs to create a separate legal entity. Notwithstanding this requirement, we agree with commenters that ACOs formed among multiple otherwise independent ACO participants, should have flexibility to establish a mechanism for shared governance as required by statute. As discussed later in this section of this final rule, we are revising our specific proposals to provide ACO greater flexibility in the composition of their governing bodies.

We also agree with commenters who suggested that we should clarify the governing body's responsibilities. An ACO's governing body shall provide oversight and strategic direction, holding management accountable for meeting the goals of the ACO, which include the three-part aim. This responsibility is broader than ''care delivery processes'' as suggested by numerous commenters and, in fact, encompasses not only care delivery, but also processes to promote evidence-based medicine, patient engagement, reporting on quality and cost, care coordination, distribution of shared savings, establishing clinical and administrative systems, among other functions. We believe that because of these broad responsibilities, the governing body is ultimately responsible for the success or failure of the ACO.

We believe that an identifiable governing body is a reasonable prerequisite for eligibility to participate in the Shared Savings Program. As discussed previously, an existing legal entity is permitted to use its current governing body. An ACO formed among otherwise independent ACO participants must establish an identifiable governing body. A governing body that is identifiable can help insulate against conflicts of interest that could potentially put the interest of an ACO participant (in an ACO formed among otherwise independent ACO participants) before the interest of the ACO. In fact, we believe an identifiable governing body will facilitate accomplishing the ACO's mission.

Comment: Numerous commenters expressed support for the requirement that the governing body include all ACO participants. For example, one commenter supported the proposal, because such a requirement would also aid CMS, FTC, and DOJ in their efforts to thwart anti-competitive behavior among ACOs.

By contrast, many commenters suggested it would be unwieldy to have representatives from each participant on the governing body, because the governing body would be difficult to operate effectively. Other commenters

stated that an ACO should not, for example, have to include each solo-practitioner physician participant on the board. Some commenters suggested that a requirement for each ACO participant to be on the governing body would permit competitors to be on each other's boards and, thus, could be anticompetitive. Many commenters indicated that we should be concerned with the outcome of the program, not with who is on an ACO's board. One commenter suggested that ACO participants be shareholders, members, or other owners of the ACO, and the ACO participants would select the governing body members. Another commenter suggested that we require an ACO to demonstrate how ACO participants have a super-majority on a medical standards committee that has responsibility to define processes to promote evidenced-based medicine and patient engagement, report on quality and cost measures, and coordinate care. However, one commenter suggested that limiting a governance voice to physicians and hospitals reduces the chances that the aim CMS expresses of reduced dependence on inpatient care will be realized. Several commenters suggested that the requirement that all participants be on the governing body may conflict with State law requirements.

Response: Although we believe that each ACO participant should have a voice in the ACO's governance, we are convinced by the comments that there are many ways to achieve this objective without requiring that each ACO participant be a member of the ACO's governing body. Thus, we will not finalize our proposal that each Medicare-enrolled ACO participant TIN, or its representative, be on the ACO's governing body. We agree with commenters that the governing bodies could become unwieldy and lose their effectiveness if we were to finalize this proposal. Such a requirement, as the commenters explained, could conflict with State law requirements regarding governing body requirements. Instead we will require an ACO to provide meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives. We disagree, however, with the comment that ACO participants who may be competitors outside of the ACO's activities necessarily raise competitive concerns when they jointly participate on the ACO's governing body. The ACO requires an integration of economic activity by ACO participants, and participants' participation in the governing body is in furtherance of that integration. Nonetheless, as explained in the final Antitrust Policy Statement, ACOs should refrain from, and implement appropriate firewalls or other safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO.

Comment: Commenters were divided in their support for the proportionate control requirement. Many commenters suggested that the proportionate share requirement is too rigid and inflexible. Several commenters stated that the concept of constituent or representative governance is antithetical to the most basic tenants of State corporation law, including the requirement of undivided loyalty applicable to members of a corporation's board of directors and the right of the shareholders of the for-profit corporation and members of nonprofit corporations to elect the governing body that is otherwise responsible for overseeing and directing the management of the corporation. Other commenters explained that the requirements are unnecessary because fiduciary decisions should be made in the best interests of the ACO as an entire organization and should not represent the individual interests of the ACO participants or any specific agendas. Other comments suggested that they would have to reconstitute their boards if we applied such a requirement. By contrast, many commenters supported this requirement if it were applied on a per participant basis, while others supported it if it were based on capital contributions.

Several commenters sought clarification as to how proportionate share should be assessed and suggested that we provide guidance to avoid tangled power struggles. Commenters suggested various methods, including: distribution of Medicare costs among the various participants in the ACO, capital contributions, per participant, equity dollars, dollars received, savings generated from operations, RVUs delivered, number of Medicare lives attributed, physicians within a TIN, or on any reasonable basis. One commenter suggested that proportionate control means representation of all specialists that provide care to an ACO's beneficiaries.

Response: In light of our decision to allow ACOs flexibility in how they establish their governing bodies, we will not finalize our proposal that each ACO participant have proportionate control of the ACO governing body.

Comment: Several commenters suggested that we require specialty practitioner representatives on the governing body, including specialists who have experience and expertise in hospice and palliative care, hematology, cataract surgery, endocrinology, surgery, mental health. Other commenters suggested that we require governing body representation of home health care and long-term care providers, the allied professions, and community stakeholders. One commenter sought a specific role for nurses on the governing body.

Another commenter suggested encouraging representation from local high-level public health officials on ACO governing bodies to help inform population health and cost-containment goals. One commenter suggested that at least one stakeholder on the board be a representative of a local hospital, regardless of whether any hospital is a participant in the ACO, because all care settings should be considered. One commenter suggested that we require ACO governing bodies to include local employers and multi-State large employer plan sponsors with experience in quality improvement and reporting and providing timely information to consumers on ACOs' governance boards to successfully improve quality, reduce unnecessary costs and drive through transformational change. Other commenters urged us to state that every professional service involved with the ACO be represented on the governing body.

Response: In light of our decision to allow ACOs flexibility in how they establish their governing bodies, we will not require representation of particular categories of providers and suppliers or other stakeholders.

Comment: Several commenters suggested we provide broad guidance on desired ACO outcomes and processes without specifying how an ACO's governing body achieves these outcomes. Other commenters suggested that we articulate the attributes of governance that we believe are important to ACOs (for example, importance of ACO participant input, the role of non-ACO participants in governance, or that ACOs that are tax-exempt entities would be expected to comply with exemption requirements) and then require the ACO to include a description in its application on how governance of ACO would align with these attributes. Other commenters suggested similar approaches, such as requiring the ACO applicant to describe its governing body and general rationale for its composition, how ACO participants and providers will achieve shared governance and decision-making such that they have significant input and control over decisions about how

care will be delivered and beneficiaries' voices heard. Commenters suggested that this flexibility would permit the ACO to determine the appropriate balance of incorporating direct participant involvement in the governance of the ACO, including board involvement, and also using operating committees where a more limited group of ACO participants would have significant input, direction and involvement in specific activities the ACO. Another commenter urged us to deem the governance structure of entities that are qualified for tax exemption under section 501(c)(3) of the Internal Revenue Code to meet the proposed governance requirements.

One commenter recommended that we require all ACOs: (1) To enact policies and procedures to ensure that physicians who participate in the ACO are free to exercise independent medical judgment; and (2) to adopt a conflict-of-interest disclosure policy to ensure that the governing body appropriately represents the interests of the ACO. One commenter suggested the ACO be governed by a Board of Directors that is elected by physicians in the ACO. Another commenter suggested in those cases where a hospital is part of an ACO, the governing board should be separate and independent of the hospital governing body. Several commenters urged us to require a majority of the ACO's governing body to be approved by ACO participants.

Response: We agree with commenters that we should articulate our views related to governance. We will finalize the requirement that the governing body provides oversight and strategic direction for the ACO, holding management accountable for meeting the goals of the ACO, which include the three-part aim. Members of the governing body shall have a fiduciary duty to put the ACO's interests before the interests of any one ACO participant or ACO provider/supplier. The governing body also must have a transparent governing process to ensure that we are able to monitor and audit the ACO as appropriate.

Final Decision: In sum, we are finalizing the requirement that an ACO must maintain an identifiable governing body with authority to execute the functions of the ACO as defined in this final rule, including but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinating care. The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities. The governing body must have a transparent governing process. The governing body members shall have a fiduciary duty to the ACO and must act consistent with that fiduciary duty. The ACO must have a conflicts of interest policy for the governing body. The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives. (§ 425.106).

d. Composition of the Governing Body

As we explained in the proposed rule, we believe that the ACO should be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries. We acknowledged, however, 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 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 addition, each of the ACO participants must choose an appropriate representative from within its organization to represent them on the governing body. We explained that these requirements would ensure that ACOs remain provider-driven, but also leave room for both non-providers and small provider groups to participate in the program.

Additionally, we proposed that ACOs provide for patient involvement in their governing process. We proposed that in order to satisfy this requirement, ACOs must include a Medicare FFS beneficiary serviced by the ACO on the ACO governing body. In order to safeguard against any conflicts of interest, we proposed that any patients included on an ACO's governing body, or an immediate family member, must not have a conflict of interest, and they must not be an ACO provider/supplier. We believed a conflict of interest standard was necessary to help effectuate our intent to ensure beneficiaries have a genuine voice in ACO governance. We sought comment on whether the requirement for beneficiary participation on the governing body should include a minimum standard for such participation. We also sought comment on the possible role of a Medicare beneficiary advisory panel to promote patient engagement in ACO governance.

Comment: Numerous commenters supported the proposed 75 percent threshold requirement for ACO participants and suppliers because they believe ACOs should be provider driven. Other commenters supported the 75 percent threshold because they believed that more than 25 percent non-participant investment could lead to disparities among Shared Savings Program stakeholders, create a conflict of interest, and impede the goal of efficient care delivery. One commenter urged us to clarify that up to 25 percent of the board can be represented by health plans and management companies. Several commenters sought clarification about how to assess the 75 percent requirement in the situation of hospital employment of providers, and whether it is the employer or the employee that must be represented.

By contrast, several commenters urged us to eliminate the 75 percent threshold because it is overly prescriptive, will prevent many existing integrated systems from applying, fails to acknowledge that governing bodies will balance representation across all the populations it covers for multiple payers that may, for instance, encourage participation of local businesses on the governing body, and will be unnecessarily disruptive to many organizations, especially those with consumer-governed boards. Several commenters suggested that we should recognize that each governing body will need to be structured differently depending on its historical makeup, the interest in participation, and other market dynamics. One commenter suggested that requiring the exact same governance structure for all ACOs risks creating inefficient bureaucracy that does not improve quality or reduce costs.

Several commenters also suggested that this restriction is likely to restrict ACO access to, and effective use of, multiple streams of capital for investing in high-value care. Other commenters argued that the restriction is likely to hinder formation of primary care physician-led organizations because they will not be able to implement effective care management and advanced information technology implementation, and lack the ability to negotiate and administer provider contracts without the participation of outside entities. Another commenter suggested the 75 percent requirement could have a chilling effect on the willingness of private payers to invest in and partner with ACOs.

Some commenters stated that the 75 percent requirement may conflict with IRS policy that requires governing bodies of tax-exempt entities to be comprised of a broad spectrum of

community members. Another commenter suggested that 501(c)(3) hospitals or health systems would find it difficult to form an ACO as a joint venture because the IRS requires those nonprofits to demonstrate that the joint venture is in the charity's interest and that charitable assets are not used for private inurement. Other commenters noted that the 75 percent requirement could conflict with State law requirements such as ones requiring governing boards of public hospitals to be elected, or that in order for nonprofit health care entities to maintain an exemption from certain State's business and occupation tax, paid employees cannot serve on the governing board. Other commenters suggested that we extend the same flexibility we proposed to provide to ACOs with regard to leadership and management structures to our governance requirements.

Response: We continue to believe that the 75-percent control requirement is necessary to ensure that ACOs are provider driven, as requested by the comments. The implication of this requirement is that non-Medicare enrolled entities, such as management companies and health plans may have less than 25 percent voting control of the ACO governing body. For example, if a hospital, two physician groups, and a health plan formed an ACO, the hospital and two physician groups must control at least 75 percent of the ACO governing body. We decline, as previously discussed, to require how the voting control of the hospital and two physicians groups is apportioned among them. Although we recognize commenters' concern that this threshold could reduce the amount of investment capital available to ACOs, we believe it strikes an appropriate balance to incent and empower ACO participants to be accountable for the success of the ACO's operations.

We also clarify that existing entity ACOs, such as a hospital employing ACO professionals, by definition, would have 100 percent control of the governing body, because the existing entity is the only member of the governing body.

Notwithstanding this requirement, we also agree with commenters that we should provide ACOs with flexibility regarding the composition of the ACO's governing body. This flexibility is discussed later in this section of this final rule and provides a means for an ACO to compose its governing body to involve ACO participants in innovative ways in ACO governance. We believe this flexibility obviates the commenters' concerns that the 75 percent threshold would conflict with laws governing the composition of tax-exempt or State-licensed entities.

Comment: In response to our request for comments on whether our requirement that 75 percent control of the governing body be held by ACO participants was an appropriate percentage, commenters suggested a variety of different percentage requirements on the governing body for certain types of ACO physicians and other health care providers. Commenters suggested that physicians occupy at least one-third, one-half, or greater than one-half of governing body seats. Other commenters suggested that primary care physicians comprise at least 50 percent of the ACO governing body and independent practices have representation proportionate to their percentage of ACO physicians, while another commenter suggested that the governing body include an equal number of primary care and specialty physicians to guarantee that ACOs' leadership structures focus on primary care, prevention, care coordination and disease management. Another commenter suggested that 50 percent of the governing body consist of physicians who have their own practice and not physicians who are employed directly or indirectly by a hospital system.

By contrast, some commenters suggested that we require a more balanced composition, with 50 percent ACO participant representation, a majority of which should be primary care providers, and 50 percent key community stakeholders who do not derive livelihood from the ACO or one of its products. Some commenters suggested that the inclusion of employer and/or labor representatives in the community stakeholder portion would also serve as a way to help prevent cost-shifting to the private sector. Another commenter suggested a bare minimum of provider representation, because anything more may bring in members to the board who do not have the requisite skill and experience to function in a leadership role.

Response: For the reasons previously discussed, we will finalize our proposal to require 75 percent control by ACO participants that are Medicare-enrolled TINs. We decline, as previously discussed, to require how the voting control will be apportioned among ACO participants.

Comment: Some commenters supported the requirement that each ACO participant choose an appropriate representative from within its organization to represent them on the governing body. Several commenters sought clarification about the requirement. For example, one commenter sought clarification that an employee of an IPA (which is a member of an ACO) can be the representative on the board. Other commenters sought clarification about the word ''organization'' in the phrase ''from within its organization,'' specifically whether organization meant each and every ACO participant's organization or the ACO as an organization.

Response: Under our proposal, we intended that a representative from each ACO participant would be included on the ACO's governing body. But, as previously discussed, we believe that ACOs should have flexibility to construct their governing bodies in a way that allows them to achieve the three-part aim in the way they see fit. Accordingly, we will eliminate the requirement that each ACO participant choose an appropriate representative from within its organization to represent it on the governing body.

Comment: Several commenters were unclear whether we were requiring that all entities with which an ACO contracts would be considered an ACO participant and therefore have a seat on the governing body. In particular, some commenters sought clarification about the interaction between an ACO and a third party that would develop the technology, systems, processes and administrative functions for the ACO. Other comments sought clarification of whether we will consider a provider system one ACO or multiple ACO participants, because the individuals within the system each have separate TINs that are eligible as ACOs in their own right.

Response: We expect that ACOs, in some instances, will contract with third parties to provide technology, systems, processes, and administrative functions for the ACO. These entities are not ACO participants as that term is defined in § 425.20 of these regulations. Accordingly, we are not requiring these third parties to be represented on the governing body. A provider system made up of multiple Medicare-enrolled TINs will have flexibility to use its existing governing body (assuming it is an existing legal entity with a pre-existing governing body) or to structure a new governing body in a way that meets the requirements for meaningful representation of its ACO participants while also enabling it to accomplish the three-part aim.

Comment: Many commenters strongly supported our proposal to require ACOs to include a beneficiary on the governing body so that the person would advocate for the local community, patient safety issues,

provide a strong, independent voice, and be part of ACO decision making. Other commenters suggested requiring even more consumer or community-based organization representation such as a plurality of the board or proportional representation based on the number of Medicare beneficiaries, such as two Medicare beneficiary representatives for every 5,000 patients assigned to the ACO, but no less than 15 percent beneficiary representation, or three beneficiaries and three local community organization representatives.

Several commenters suggested that one beneficiary on the board is insufficient. Other commenters argued that together beneficiaries and consumer advocates must possess a sufficient number of seats on the governing body to enable them to substantively influence an ACO and its operations, because beneficiary representatives and consumer advocates bring distinct perspectives to the table. Other commenters suggested that the ACO describe in its application how it would have diverse, balanced, and effective consumer representation in the ACO's governance.

Other commenters objected to our proposal to deem ACOs as having met the requirement to partner with community stakeholders simply by including a community stakeholder on the governing board. These comments argue that ACOs will serve a diverse population with a range of needs, preferences, and values and, thus, one representative will not be able to speak for the entire community on all issues. These commenters urged us to require that ACOs develop partnerships with community-based organizations that—(1) operate within a single local or regional community; (2) are representative of a community or significant segments of a community; and (3) provide health, educational, personal growth, and improvement, social welfare, self-help for the disadvantaged or related services to individuals in the community.

Several commenters expressed concern about how the beneficiary representative would be chosen. For example, one commenter sought clarification on how we would know that the chosen beneficiary is truly representative of the beneficiary population served by the ACO. Another commenter expressed concern about the potential influence of this board on the consumer representative. Some commenters stated it would make more sense for the beneficiary representative to have healthcare knowledge or business experience. One commenter suggested that non-medical oriented individuals will likely promote their special projects that they perceive as beneficial to their own goals and aims.

One commenter sought clarification about whether beneficiary and/or community organization is counted toward the 75 percent threshold or if it is in the 25 percent non-participant group.

By contrast, many comments stated our proposed requirement was too prescriptive. Commenters indicated that such a requirement could: (1) Mean that a clinically integrated physician network would have to restructure its bylaws and thus re-contract with its entire physician network; (2) place the beneficiary in an inappropriate position to be voting on decisions of the organization's non-ACO lines of business; (3) conflict with State law which requires only licensed medical professionals to govern the professional corporation; (4) conflict with State and local laws that dictate composition of public hospital/health system boards and/or restrict the authority those boards may be able to delegate (given their authority over taxpayer funds); or (5) result in a potential HIPAA violation.

These commenters suggested that there are more effective ways to obtain beneficiary representation such as through creation of a committee of participants and/or beneficiaries which could accomplish the same purpose without the necessity of a board role. They recommended creating non-voting and ongoing advisory groups of beneficiaries rather than requiring an ACO to include a single beneficiary on the governing body. One commenter suggested that we define lack of a ''conflict of interest.''

Response: We continue to believe that a focus on the beneficiary in all facets of ACO governance will be critical for ACOs to achieve the three-part aim. Therefore, we finalize our proposal to require beneficiary representation on the governing body, with an option (discussed later in this final rule) to allow for flexibility for those ACOs that seek innovative ways to involve beneficiaries in ACO governance.

We decline the suggestions to increase the beneficiary representation requirement, because we believe the proposal achieves our objective but still permits ACOs flexibility to structure their governing bodies appropriately. We encourage all ACOs to consider seriously how to provide other opportunities for beneficiaries to be involved further in ACO governance in addition to the seat on the governing body. We also clarify that, as we proposed, the beneficiary representative (like all members on the governing body as discussed previously) must not have a conflict of interest, such that he or she places his or her own interest, or an interest of an immediate family member, above the ACO's mission. In addition, the beneficiary representative cannot be an ACO provider/supplier within the ACO's network.

We recognize commenters' concerns that requiring a beneficiary on the governing body could conflict with State corporate practice of medicine laws or other local laws regarding, for instance, governing body requirements for public health or higher education institutions. In addition, there could be other reasons that beneficiary representation on an ACO's governing body may not be feasible. For these reasons, we agree with commenters that it is appropriate to provide flexibility regarding the composition of ACO governing bodies. Accordingly, an ACO that seeks to compose its governing body in such a way that it does not meet either the requirement regarding 75 percent ACO participant control or the requirement regarding beneficiary representation on the governing body would be able to describe in its application how the proposed structure of its governing body would involve ACO participants in innovative ways in ACO governance and provide a meaningful opportunity for beneficiaries to participate in the governance of the ACO. For example, this flexibility would allow ACOs that operate in States with Corporate Practice of Medicine restrictions to structure beneficiary representation accordingly and it also would allow for consumer-driven boards that have more than 25 percent consumer representation. This option could also be used by existing entities to explain why they should not be required to reconfigure their board if they have other means of addressing the consumer perspective in governance.

Final Decision: In summary, we will finalize our proposals that at least 75 percent control of the ACO's governing body must be held by the ACO's participants. The governing body of the ACO must be separate and unique to the ACO in the cases where the ACO comprises multiple, otherwise independent entities that are not under common control (for example, several independent physician group practices). However, the members of the governing body may serve in a similar or complementary manner for a participant in the ACO. Each ACO should provide for beneficiary representation on its governing body. In cases in which the composition of an ACO's governing

body does not meet the 75 percent ACO participant control threshold or include the required beneficiary governing body representation, the ACO must describe why it seeks to differ from the established requirements and how the ACO will involve ACO participants in innovative ways in ACO governance and/or provide for meaningful participation in ACO governance by Medicare beneficiaries. (§ 425.106).

4. Leadership and Management Structure

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.'' In the proposed rule, we stated that we believed 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.

We drew from two sources to develop our proposals for ACO leadership and management structures. We first highlighted those factors that participants in the PGP demonstration identified as critical to improving quality of care and the opportunity to share savings. Second, we discussed the criteria developed by the Antitrust Agencies to assess whether collaborations of otherwise competing health care providers are likely to, or do, enable their collaborators jointly to achieve cost efficiencies and quality improvements. We explained that the intent of the Shared Savings Program and the focus of antitrust enforcement are both aimed at ensuring that collaborations between health care providers result in improved coordination of care, lower costs, and higher quality, including through investment in infrastructure and redesigned care processes for high quality and efficient service delivery. We stated in the proposed rule that the Antitrust Agencies' criteria provide insight into the leadership and management structures, including clinical and administrative systems, necessary for ACOs to achieve the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.

We stated that it is in the public interest to harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the similar antitrust criteria on clinical integration, because competition between ACOs is expected to have significant benefits for Medicare beneficiaries. Further, because ACOs that operate in the Shared Savings Program are likely to use the same organizational structure and clinical care practices to serve both Medicare beneficiaries and consumers covered by commercial insurance, the certainty created by harmonizing our eligibility criteria with antitrust criteria will help to reduce the likelihood that an ACO organization participating in the Shared Savings Program will be challenged as per se illegal under the antitrust laws, which could prevent the ACO from fulfilling the term of its agreement under the Shared Savings Program.

Thus, in order to meet the requirements in section 1899(b)(2)(F) of the Act that an ACO have a leadership and management structure that includes clinical and administrative systems, we proposed that an ACO meet the following criteria:

- The ACO's operations would be managed by an executive, officer, manager, or general partner, whose appointment and removal are under the control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.
- Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present on a regular basis in an established location of the ACO.
- ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success.
- The ACO would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program.
- The ACO would develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, and lower growth in expenditures.
- The ACO would have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of service.

In order to determine an ACO's compliance with these requirements, as part of the application process, we proposed that an ACO would submit all of the following:

- ACO documents (for example, participation agreements, employment contracts, and operating policies) that describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO, how the opportunity to receive shared savings will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and the evidenced-based clinical guidelines.
- Documents that describe the scope and scale of the quality assurance and clinical integration program, including documents that describe all relevant clinical integration program systems and processes.
- Supporting materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including the names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders.
- Evidence that the ACO has a board-certified physician as its medical director who is licensed in the State in which the ACO resides and that a principal CMS liaison is identified in its leadership structure.
- Evidence that the governing body includes persons who represent the ACO participants, and that these ACO participants hold at least 75 percent control of the governing body.

Additionally, upon request, the ACO would also be required to provide copies of the following documents:

- Documents effectuating the ACO's formation and operation, including charters, by-laws, articles of incorporation, and partnership, joint venture, management, or asset purchase agreements.
- Descriptions of the remedial processes that will apply when ACO participants and ACO providers/suppliers fail to comply with the ACO's internal procedures and performance standards, including corrective action plans and the circumstances under which expulsion could occur.

We also proposed to allow ACOs with innovative leadership and management structures to describe an alternative mechanism for how their leadership and management structure would conduct the activities noted previously in order to achieve the same goals so that they could be given consideration in the application process. That is, an organization that does not have one or more of the following: An executive, officer, manager, or general partner; senior-level medical director; or

physician-directed quality assurance and process improvement committee, would be required in its application to describe how the ACO will perform these functions without such leadership. Additionally, we sought comment on the requirement for submission of certain documents as noted previously and whether an alternative method could be used to verify compliance with requirements. We also requested comment on the leadership and management structure and whether the compliance burden associated with these requirements would discourage participation, hinder innovative organizational structures, or whether there are other or alternative leadership and management requirements that would enable these organizations to meet the three-part aim.

Comment: Some commenters suggested that we require that a physician or a surgeon licensed in the State in which the ACO is organized serve as either the CEO or president of the ACO and that a physician or a surgeon licensed in the State in which the ACO is organized serve as the Chair of the Board of Directors of the ACO. Other commenters recommended that CMS require that primary care physicians be in executive leadership positions of the ACO. Other commenters suggested that we require personnel with health information management experience to be part of the ACO's leadership.

Response: In light of our decision to allow ACOs flexibility in how they establish their governing bodies, we also believe that ACOs should have flexibility to determine their leadership and management structure. We understand commenters' concerns, but we decline to specify additional requirements as suggested by the commenters for ACO leadership and management.

Comment: Many commenters strongly supported the proposed requirement of senior-level medical director with responsibility for clinical management and oversight. Several commenters suggested removing the full-time requirement, because the ACO may not have the volume to support a full-time position, it is costly and inconsistent with the diverse needs of each ACO, and there is little evidence to suggest that a small to mid-size ACO is likely to need a full time senior-level medical director who is physically present on a regular basis at an established ACO location.

Many commenters supported a part-time requirement, flexible time requirement, or no time requirement. One commenter suggested that the duties of a ''full time medical director'' include the provision of direct clinical care to patients. One commenter suggested eliminating the full time requirement, as long as the medical director devotes sufficient time to fulfilling their ACO related responsibilities. Another commenter suggested that the focus should be on whether the required coordination of care processes are in place and functional at a core level, rather than who is directing them.

Several comments suggested removing the requirement that the medical director be a physician because the Act does not require physician leadership, nor is there evidence suggesting physician leadership is necessary. Several commenters suggested the medical director could be any qualified health care professional.

A few comments suggested strengthening the requirements for clinical oversight and requiring that the director demonstrate an understanding of the core concepts of medical management or have managerial experience, advanced management degree, or certification in medical management and system leadership. One commenter suggested that physician leadership show that it has geriatric competencies, to ensure that patients with dementia and Alzheimer's disease do not receive poorer care.

A few comments suggested that we: (1) Not require the medical director to be licensed in the State because if a medical director has been effective in excelling in services in one State and seeks to expand those services into another State, CMS would be ill-advised to prevent this from occurring; and (2) not require board certification but instead allow a physician who has acquired certification in medical management or quality improvement to be the medical director.

Some commenters sought clarification as to whether the medical director must be licensed in every State in which a multi-State ACO operates and whether the medical director must be on-site at each location at which the ACO provides services (if a multi-site ACO).

Response: We believe physician leadership of clinical management and oversight is important to an ACO's ability to achieve the three-part aim and we will finalize the proposed requirement that an ACO have a senior-level medical director who is a board-certified physician. However, we understand that this requirement may pose an additional financial burden, particularly in small or rural ACOs. Therefore, we are modifying our original proposal to eliminate the full time requirement. Instead, we will require that clinical management and oversight be managed by a senior-level medical director who is one of the ACO's physicians. We decline to require additional qualifications for the medical director, because such qualification may be burdensome for small and rural ACOs. However, we are maintaining the requirement that the medical director be board-certified and licensed in one of the States in which the ACO operates. We believe such certification and licensure are necessary to establish credibility among physicians in the ACO. Further, we clarify that an ''on site'' physician is one who is present at any clinic, office, or other location participating in the ACO.

Comment: Some commenters supported the requirement for a physician-directed quality assurance and process improvement committee. Several comments stated that physician-led quality and clinical process improvement activities are crucial to building trust and credibility with physicians and beneficiaries, as well as necessary ingredients to achieving the quality and beneficiary satisfaction targets set by the program.

By contrast, other commenters believed that such a physician-led committee would be onerous in rural areas and that safety net providers should have some flexibility in meeting these requirements. Several commenters suggested removing the requirement for physician leadership and instead requiring leadership by any qualified healthcare professional. Some comments suggested requiring the director to demonstrate special training or certification in quality improvement.

Response: We acknowledge commenters' concerns that a committee could be burdensome for certain ACOs and that quality improvement activities can be directed by non-physician leadership. In particular, we are persuaded by commenters who suggested that many existing and successful quality improvement efforts are not physician-led. Accordingly, we will eliminate the requirement for ACOs to establish such a committee. Instead, as part of its application, an ACO will be required to describe how it will establish and maintain an ongoing quality assurance and improvement program, led by an appropriately qualified health care professional. We believe these modifications will provide ACOs with greater flexibility to meet this requirement.

Comment: Some commenters supported our proposal to learn from the Antitrust Agencies' clinical integration requirements to help specify

the necessary ''clinical and administrative systems'' that are required to be part of the ACO's leadership and management structure. These commenters recognized that ''success will be determined by the engagement and commitment of practicing physicians.'' Indeed, one commenter explained that unregulated clinical integration was likely to lead to the greater vertical consolidation of provider markets, which in turn will fuel cost growth, making health care less affordable for private payers.

By contrast, several commenters contended that the proposed rule's decision to rely, in part, on the Antitrust Agencies' clinical integration requirements for ''clinical and administrative'' systems was in error. These and other commenters opposed the proposed clinical integration requirements as overly prescriptive, unnecessary, likely to limit innovation in design and implementation of ACOs and unrelated to the three-part aim. However, many of these commenters acknowledge that it is a step forward that the proposed Antitrust Policy Statement states that an ACO that meets CMS criteria will be found to be sufficiently ''integrated'' to meet part of the test for avoiding antitrust enforcement actions. Several commenters also suggested that even if there are changes to the ACO program to make it more attractive financially, these barriers to clinical integration will impede a robust response to the ACO program.

One commenter explained that real clinical integration is evidenced by patient coordination of care across health care settings, providers, and suppliers and is best shown when there is a structure in place that is patient-focused and where clinicians collaborate on best practices in an effort to furnish higher quality care that they likely would not achieve if working independently. This commenter and others suggested that we focus on the statutorily required processes regarding reporting quality measures, promoting evidence-based patient processes, and coordinating care, thus making separate clinical integration requirements moot.

Several commenters suggested that we eliminate the requirements regarding clinical integration and instead describe, at a very high level, examples of possible ways an ACO could meet the three-part aim. Some commenters suggested that the Antitrust Agencies specify which criteria are related to antitrust issues and which are applicable to all clinically integrated health care organizations. One commenter suggested that CMS, as a purchaser of health care services, should negotiate targets for performance at a higher level and not place requirements on how ACOs achieve these targets. Several commenters suggested we work with the Antitrust Agencies to create more flexibility for physicians to join together to provide services. A commenter argued that participation in the Shared Savings Program, in itself, is an undertaking of meaningful financial integration, thus rendering the need for compliance with clinical integration unnecessary to avoid per se condemnation.

Response: We disagree with the commenters' suggestion that relying, in part, on the Antitrust Agencies' clinical integration requirements for ''clinical and administrative'' systems is overly prescriptive, unnecessary, or likely to limit innovation in ACO design. As we explained in the proposed rule, the purposes of the Shared Savings Program and the Antitrust Agencies' clinical integration requirements are complementary and, indeed, mutually reinforcing. The purposes of the Shared Savings Program are to promote accountability for a patient population, coordinate items and services furnished to beneficiaries under Medicare Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. The Antitrust Agencies' clinical integration criteria require participants to show a degree of interaction and interdependence among providers in their provision of medical services that enables them to jointly achieve cost efficiencies and quality improvements. We do not see how ACO participants and ACO providers/suppliers could achieve the statutory goals of the Shared Savings Program without showing a degree of interaction and interdependence in their joint provision of medical services such that they provide high quality and efficient service delivery. Many commenters agreed with this conclusion and we disagree with the commenters that suggested otherwise.

We also agree with commenters that the four statutorily required processes (section 1899(b)(2)(G) of the Act) to promote evidence-based medicine, report cost and quality metrics, promote patient engagement, and coordinate care overlap and are consistent with our proposed clinical integration criteria. Accordingly, we are aligning our final requirements regarding sufficient ''clinical and administrative systems'' with our final requirements regarding these four required processes. These required processes are discussed later in this section of the final rule.

We disagree with the commenter that participation in the Shared Savings Program is an undertaking of meaningful financial integration. Because ACO participants and ACO providers/suppliers will continue to receive FFS payments and are required only to have a mechanism to receive and distribute shared savings, they will not necessarily be sharing substantial financial risk, which is the hallmark of financial integration.

Comment: Some commenters suggested that we provide concrete standards as to what a meaningful commitment is (especially a meaningful human investment). Another commenter suggested that those ACO providers/suppliers providing a meaningful financial commitment should receive increased shared savings.

A commenter questioned whether it is sufficient to demonstrate a meaningful commitment if a provider agrees to participate contractually in an ACO and to comply with the ACO's clinical, performance, and administrative standards.

A commenter suggested we revise our interpretation of ''meaningful commitment to the ACO's clinical integration,'' because financial and human capital are insufficient to show clinical integration; rather, real clinical integration is evidenced in patient coordination of care across health care settings, providers, and suppliers.

Some commenters queried how a specialist or other health care professional can show ''meaningful commitment'' if they are in more than one ACO. Other commenters suggested that the level of observable commitment is neither a precursor to clinical activity nor the outcome.

Response: We continue to believe that each ACO participant and ACO provider/supplier must demonstrate a meaningful commitment (for example, time, effort, or financial) to the ACO's mission to ensure its likely success so that the ACO participant and/or ACO provider/supplier will have a stake in ensuring the ACO achieves its mission. Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant or ACO provider/supplier to take the actions necessary to help the ACO achieve its mission. A meaningful commitment may be evidenced by, for example—

- Financial investment such as capital contributions for ACO infrastructure information systems, office hardware, computer software,

ACO staff, training program, or any other aspect of the ACO's operations where that investment provides the ACO participant or provider/supplier with a sufficient stake in the successful operation of the ACO such that the potential loss or recoupment of the investment is likely to motivate the participant or provider/supplier to achieve the mission of the ACO; and

• Human investment such as serving on the ACO's governing body; serving on committees relating to the establishment, implementation, monitoring or enforcement of the ACO's evidence-based medical practice or clinical guidelines; or otherwise participating in other aspects of the ACO's operations, such as definition of processes to promote patient engagement, care coordination, or internally reporting on cost and quality metrics, to a degree that evidences a personal investment in ensuring that the ACO achieves its goals.

We also believe that a commitment can be meaningful when ACO participants and ACO providers/suppliers agree to comply with and implement the ACO's required processes and are accountable for meeting the ACO's performance standards. By doing so, we believe that they will be motivated to achieve the ACO's internal performance standards and to comply with the processes required by section 1899(b)(2)(G) of the Act (as discussed later in this section). Indeed, we fail to see how the required processes discussed later in this final rule could be effectuated unless ACO providers/suppliers meaningfully commit to implement, adhere to, and be accountable for the ACO's evidenced-based medical guidelines, care coordination procedures, patient engagement processes, and reporting of cost and quality that are essential to meeting the three-part aim.

We also clarify that an ACO provider/supplier can contractually agree to work with one or more ACOs by agreeing to implement, adhere to, and be accountable for that ACO's statutorily required processes. We disagree with the commenter's suggestion that the level of observable commitment is neither a precursor to clinical activity nor to outcome. We do not see how an ACO could achieve its mission if its providers and suppliers do not agree to comply with and implement the ACO's required processes. Such a commitment is necessary, although insufficient in and of itself, to ensure that an ACO achieves the three-part aim.

Comment: Several commenters suggested that the requirement that ACOs include descriptions in their applications of how they will satisfy certain criteria and make documents available is too burdensome and creates a barrier to participation, especially for safety net providers and many smaller and non-hospital-based applicants. Some commenters asked what we will do with the information (for example, employment contracts).

But several comments suggested we strengthen the application requirement. For example, these commenters stated that an ACO should be required to detail how it plans to partner with community-based organizations, and to detail the kinds of processes it will use to coordinate the care of Medicare beneficiaries with post-acute care providers.

Another commenter suggested self-attestation for the many requested documents to show the leadership and management structures. Other commenters urged us to use NCQA's ACO certification standards to deem an ACO as acceptable and to work with NCQA to eliminate duplicating requirements and aligning accreditations.

Response: We acknowledge commenters' concerns that the proposed documentation requests may be burdensome for certain ACOs. Accordingly, we have aligned our proposed documentation requests regarding clinical and administrative systems with the statutory processes that are described in this section. We believe that this streamlining of document requests addresses the commenters' suggestions for additional detail regarding certain clinical and administrative processes. It also obviates the need to rely NCQA's ACO certification standards. Notwithstanding this alignment, we continue to believe that ACOs should submit certain documentation regarding their clinical and administrative systems to ensure that the ACO meets the eligibility requirements, has the requisite clinical leadership, and has a reasonable chance of achieving the three-part aim. In addition, we will use the documents to assess whether ACO participants and ACO provider/supplier(s) have the requisite meaningful commitment to the mission of the ACO.

Comment: Several commenters applauded our proposal to consider an innovative ACO with a management structure not meeting the proposed leadership and management requirements. As noted previously, many commenters suggested that the leadership and management requirements were overly prescriptive. Thus, many commenters supported the innovative option proposal.

Response: We will finalize our proposal to allow ACO applicants to describe innovative leadership and management structures that do not meet the final rule's leadership and management structures in order to encourage innovation in ACO leadership and management structures.

Final Decision: We will finalize the requirement that the ACO's operations be managed by an executive, officer, manager, or general partner, whose appointment and removal are under the control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes. In addition, clinical management and oversight must be managed by a senior-level medical director who is one of the ACO's physicians, who is physically present on a regular basis in an established ACO location, and who is a board-certified physician and licensed in one of the States in which the ACO operates.

As part of its application, an ACO will be required to describe how it will establish and maintain an ongoing quality assurance and improvement program, led by an appropriately qualified health care professional. ACO participants and ACO providers/suppliers must demonstrate a meaningful commitment to the mission of the ACO. A meaningful commitment can be shown when ACO participants and ACO providers/suppliers agree to comply with and implement the ACO's processes required by section 1899(b)(2)(G) of the Act and are held accountable for meeting the ACO's performance standards for each required process as defined later in this section.

As part of their applications, ACOs must submit certain documentation regarding their leadership and management structures, including clinical and administrative systems, to ensure that the ACO meets the eligibility requirements. We are finalizing the following document requests to effectuate our leadership and management structure requirements:

• ACO documents (for example, participation agreements, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO.

• Supporting 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.

Additionally, upon request, the ACO may also be required to provide copies of documents effectuating the ACO's formation and operation, including charters, by-laws, articles of incorporation, and partnership, joint venture, management, or asset purchase agreements.

We also will finalize our proposal to allow ACO applicants to describe innovative leadership and management structures that do not meet the final rule's leadership and management requirements. (§ 425.108, § 425.112, and § 425.204).

5. Processes To Promote Evidence-Based Medicine, Patient Engagement, Reporting, Coordination of Care, and Demonstrating Patient-Centeredness

Section 1899(b)(2) of the Act establishes a number of requirements which ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. Specifically, section 1899(b)(2)(G) of the Act requires an ACO to define processes to: Promote evidence-based medicine and patient engagement; report on quality and cost measures; and coordinate care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies.

We proposed that to meet the requirements under section 1899(b)(2)(G) of the Act, the ACO must document in its application its plans to: (1) Promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. We proposed to allow ACOs the flexibility to choose the tools for meeting these requirements that are most appropriate for their practitioners and patient populations. In addition, we proposed that the required documentation present convincing evidence of concrete and effective plans to satisfy these requirements and that the documentation provide the specific processes and criteria that the ACO intends to use. This documentation was necessary because we wanted to ensure such processes would include provisions for internal assessment of cost and quality of care within the ACO, and that the ACO would employ these assessments in continuous improvement of the ACO's care practices. We explained in the proposed rule that as we learn more about successful strategies in these areas, and as we have more experience assessing specific critical elements for success, the Shared Savings Program eligibility requirements with regard to section 1899(b)(2)(G) of the Act may be revised. We also specifically solicited comment on whether more prescriptive criteria may be appropriate for meeting some or all of these requirements under section 1899(b)(2)(G) of the Act for future rulemaking.

In addition, section 1899(b)(2)(H) of the Act requires an ACO to ''demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.'' We explained that a patient-centered, or person-centered, orientation could be defined as care that incorporates the values of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care. We drew from the work of the Institute of Medicine and the principles articulated by the National Partnership for Women and Families to develop our proposals. We explained that the statutory requirement for ''patient-centeredness criteria'' means that patient-centered care must be promoted by the ACO's governing body and integrated into practice by leadership and management working with the organization's health care teams.

We proposed that an ACO would be considered patient-centered if it has all of the following:

- A beneficiary experience of care survey in place and a description in the ACO application of how the survey results will be used to improve care over time.
- Patient involvement in ACO governance. The ACO would be required to have a Medicare beneficiary on the governing board.
- A process for evaluating the health needs of the ACO's assigned population, including consideration of diversity in its patient populations, and a plan to address the needs of its population. A description of this process must be included in the application, along with a description of how the ACO would consider diversity in its patient population and how it plans to address its population needs.
- Systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs.
- A mechanism in place for the coordination of care (for example, via use of enabling technologies or care coordinators). In addition, the ACO should have a process in place (or clear path to develop such a process) to electronically exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO, consistent with meaningful use requirements under the Electronic Health Records (EHR) Incentive program.
- A process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them. This process should allow for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities.
- Written standards in place for beneficiary access and communication and a process in place for beneficiaries to access their medical records.
- Internal processes in place for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time.

We explained that this list provides a comprehensive set of criteria for realizing and demonstrating patient-centeredness in the operation of an ACO. We solicited comment on these criteria.

We also noted that there is substantial overlap and alignment between the processes ACOs are required to define under section 1899(b)(2)(G) of the Act and both the proposed patient-centeredness criteria (as defined by the Secretary in accordance with section 1899(b)(2)(H) of the Act) and the clinical and administrative systems that are to be in place in the ACO's leadership and management structure as required by section 1899(b)(2)(F) of the Act. Accordingly the following comment and responses discussion includes a discussion of not only the required process, but also the patient-centeredness criteria and the necessary clinical and administrative systems.

Comment: Commenters suggested that we require a sufficient level of detail on processes that ACOs are required to define. Several commenters suggested that we require ACOs to evaluate their own practices and make adjustments as necessary and hold ACOs accountable for adhering to their stated plans. Other commenters expressed concerns that ACOs will need clear and certain guidance, including technical support, on the processes to promote: Evidence-based medicine, patient engagement, reports on quality and cost measures, and the coordination of care. Other commenters explained that patient coordination of care across health care

settings, providers, and suppliers is best shown when there is a structure in place that is patient-focused and where clinicians collaborate on best practices in an effort to furnish higher quality care that they likely would not achieve if working independently. These commenters suggested that our requirements regarding the four statutorily required processes can help ensure that there is a structure in place to ensure the likelihood that an ACO can achieve the three-part aim.

Response: Although we understand the request by some commenters that we develop a more prescriptive approach to define each of the four processes, we are concerned that such an approach would be premature and potentially impede innovation and the goals of this program. ACOs should retain the flexibility to establish processes that are best suited to their practice and patient population.

Final Decision: We will finalize our proposal requiring that in order to be eligible to participate in the Shared Savings Program, the ACO must provide documentation in its application describing its plans to: (1) Promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. As part of these processes, an ACO shall adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams. These plans must include how the ACO intends to require ACO participants and ACO providers/suppliers to comply with and implement each process (and sub element thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply. In addition, these plans must describe how such processes will include provisions for internal assessment of cost and quality of care within the ACO and how the ACO would employ these assessments in continuous improvement of the ACO's care practices. (§ 425.112).

a. Processes To Promote Evidence-Based Medicine

As stated previously, section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to promote evidence-based medicine * * *.'' We explained in the proposed rule that evidence-based medicine can be generally defined as the application of the best available evidence gained from the scientific method to clinical decision-making. We proposed that as part of the application, the ACO would describe the evidence-based guidelines it intends to establish, implement, and periodically update.

Comment: Nearly all comments received supported processes to promote evidence-based medicine. Some commenters also suggested that the ACO's evidence-based guidelines apply to a broad range of conditions that are found in the beneficiary population served by the ACO. In addition, some commenters suggested that we provide additional guidance on the development and implementation these guidelines and processes by: (1) Requiring sufficient level of detail on processes and tools that will be utilized; (2) requiring ACOs to evaluate the practices and make adjustments as necessary; (3) including measures that assess the intended outcomes of these practices in the quality reporting requirement; and holding ACOs accountable for adhering to their stated plans.

Additionally, several commenters recommended that these processes be more prescriptive and include: Measures for improvement to functional status, suggested tools for monitoring decision support, and specifications for baseline evidence-based guidelines. Other commenters suggested that we establish guidelines for how ACOs should establish their evidence-based medicine. For example, one commenter explained why the organized medical staff of a hospital in which an ACO participates should review and approve all medical protocols and all other quality programs concerning inpatient care at that hospital. Other commenters suggested that we require specialist involvement in the development of these clinical guidelines and processes so that the guidelines reflect appropriate standards of care for their patients and so that new treatments are not discouraged or disadvantaged. Another commenter suggested we require that clinical practice guidelines used by ACOs located in the same geographical area be consistent so that specialists may be able to participate in more than one ACO. One comment suggested that we adopt a similar set of criteria to evaluate the evidence-based approaches of ACOs similar to the one the Institute of Medicine (IOM) recently released in its consensus report, ''Clinical Practice Guidelines We Can Trust,'' that details criteria that all evidence-based guidelines should meet.

One commenter suggested broadening the definition of the term ''evidence-based medicine'' to include best practices regarding evidence-based psychosocial interventions not generally included as medicine. One commenter suggested that we require that the application specify how the leadership structure will assure linkage and involvement with local and State health agencies.

One comment recommended that ACOs that have met requirements for NCQA Medical Home recognition be eligible to use the same ''short form'' of documentation of these capabilities that will be available to the PGP demonstration practices.

Response: As discussed previously, we believe it is important that ACOs retain the flexibility to define processes that are best suited to their own practices and patient populations. Thus, for the requirements under section 1899(b)(2)(G) of the Act, ACOs must provide documentation in their respective applications describing how they plan to define, establish, implement, and periodically update processes to promote evidence-based medicine applicable to ACO participants and ACO providers/suppliers as opposed to the establishment of more prescriptive guidelines regarding the processes of evidence-based medicine. We agree with commenters that for these guidelines to have an impact they must cover diagnoses found in the beneficiary population assigned to the ACO. We believe that the guidelines should address diagnoses with significant potential for the ACO to achieve quality improvements, while also accounting for the circumstances of individual beneficiaries. For the reasons stated previously, we decline, however, to establish the processes by which ACOs should develop these evidence-based medicine guidelines. We would consider an ACO that has met the requirements for NCQA Medical Home recognition well on its way to demonstrating that it has processes in place that support evidence-based guidelines, but we will still need to evaluate them in the context of the Shared Savings Program eligibility requirements.

Final Decision: As previously discussed, to be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement, and periodically update its processes to promote evidence-based medicine. These guidelines must cover diagnoses with significant potential for the ACO to achieve quality improvements, taking into account the circumstances of individual beneficiaries. (§ 425.112).

b. Processes To Promote Patient Engagement

Section 1899(b)(2)(G) of the Act also requires an ACO to ''define processes to promote * * * patient engagement.'' We described in the proposed rule that the term ''patient engagement'' is the active participation of patients and their families in the process of making medical decisions. We explained that measures for promoting patient engagement may include, but are not limited to, the use of decision support tools and shared decision making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions. Patient engagement also includes methods for fostering ''health literacy'' in patients and their families. We proposed that as part of its application, the ACO would describe the patient engagement processes it intends to establish, implement, and periodically update.

Related to the process to promote patient engagement, we also proposed that ACOs have a beneficiary experience of care survey in place and that the ACO's application should describe how the ACO will use the survey results to improve care over time. We explained in the proposed rule that surveys are important tools for assessing beneficiary experience of care and outcomes. As part of the requirement to implement a beneficiary experience of care survey, we proposed to require ACOs to collect and report on measures of beneficiaries' experience of care and to submit their plan on how they will promote, assess, and continually improve in weak areas identified by the survey.

Specifically we proposed that ACOs will be required to use the CAHPS survey. We also proposed to require the adoption of an appropriate functional status survey module that may be incorporated into the CAHPS survey. As further discussed in section II.F. of this final rule, scoring on the patient experience of care survey would become part of the assessment of the ACO's quality performance.

Promoting patient engagement would also include a requirement that ACOs provide for patient involvement in their governing processes. We proposed that ACOs would be required to demonstrate a partnership with Medicare FFS beneficiaries by having representation by a Medicare beneficiary serviced by the ACO, in the ACO governing body. In order to safeguard against any conflicts of interest, we proposed that any patient(s) included in an ACO's governing body, or an immediate family member, must not have any conflict of interest, and they may not be an ACO provider/supplier within the ACO's network. Section II.B.3. of this final rule discusses these issues in full.

In addition to these two proposals relating to processes for patient engagement, we proposed four other requirements relating to patient-centeredness that overlap substantially with our proposals regarding patient engagement. These processes include: (1) Evaluating the health needs of the ACO's assigned population, including consideration of diversity in its patient populations, and a plan to address the needs of its population; (2) communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them; (3) engaging beneficiaries in shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities; and (4) having written standards in place for beneficiary communications and allowing beneficiary access to their medical record.

As part of the application, we proposed that the ACO would describe the patient engagement processes it intends to establish, implement, and periodically update.

Comment: Commenters supported our proposal requiring that an ACO describe, in its application, its process for evaluating the health needs of the population, including consideration of diversity in its patient populations, and a plan to address the needs of its Medicare population. Several comments suggest that certain populations, such as tribal populations, have a disproportionate share of diversity and recommended including specific measures to account for the diversity in their Medicare population.

Response: We agree with the comments received that certain beneficiary populations will be more diverse than others, which is why we proposed to provide ACOs with the flexibility to describe the processes that will be most effective in evaluating their patient population as opposed to prescriptively identifying specific measures for all ACOs.

Comment: Several commenters explained that ACOs must recognize that the needs of a diverse population are based on many factors, such as race, gender, gender identity or expression, sexual orientation, disability, income status, English proficiency, and others. These commenters, and others, suggested that we develop an objective set of criteria for the evaluation of population health needs and consideration of diversity.

Response: We agree with commenters that true patient engagement requires sensitivity to the many diverse factors that can affect a specific patient population and the appropriate care to address the health needs of that population. We explained in the proposed rule that several institutions and associations such as the National Committee for Quality Assurance (NCQA) and AHRQ have made recommendations regarding evaluation of population health and diversity. Establishing partnerships with a State or local health department which performs community health needs assessments and applying these findings to the ACO's population and activities may be another viable option for meeting this criterion. Given this broad range of available resources, we decline to develop a set of evaluation criteria to assess the health needs of an ACO's patient population.

Comment: Commenters supported requiring ACOs to demonstrate processes to promote patient engagement relating to communicating clinical knowledge, shared decision making, and beneficiary access to medical records. Some commenters expressed concern that we were allowing too much latitude in defining these processes. These commenters recommended more guidance in areas where there is evidence of best practices. Comments also recommended that in order for the benefits of adherence to processes to promote patient engagement to be realized, patients and families need to be incentivized to actively participate in their own health care.

Response: We believe it is important that ACOs retain the flexibility to establish processes that are best suited to their own practices and patient populations. Additionally, the very act of educating and engaging patients in the decision making processes associated with their own health care needs should sufficiently incentivize patients to actively engage in prospective treatment approaches in the light of their own values and convictions. Therefore, we decline to impose additional requirements in this area.

Final Decision: To be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement, and periodically update processes to promote patient engagement. In its application an ACO must describe how it intends to address all of the following areas: (a) Evaluating the health needs of the ACO's assigned population; (b) communicating clinical knowledge/evidence-based medicine to

beneficiaries; (c) beneficiary engagement and shared decision-making; and (d) written standards for beneficiary access and communication, and a process in place for beneficiaries to access their medical record. (§ 425.112).

c. Processes To Report on Quality and Cost Measures

Section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to * * * report on quality and cost measures.'' We explained in the proposed rule that processes that may be used for reporting on quality and cost measures may include, but are not limited to, developing a population health data management capability, or implementing practice and physician level data capabilities with point-of-service (POS) reminder systems to drive improvement in quality and cost outcomes. We stated that we expect ACOs to be able to monitor both costs and quality internally and to make appropriate modifications based upon their collection of such information.

In our discussion of required clinical and administrative systems, we proposed that an ACO would have an infrastructure that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of care.

We proposed that as part of the application, the ACO would describe its process to report internally on quality and cost measures, and how it intends to use that process to respond to the needs of its Medicare population and to make modifications in its care delivery.

Comment: Several commenters suggested that we outline quality reporting requirements for the Shared Savings Program. Other commenters suggested that an ACO detail its plans to manage information technology (IT) use and to identify personnel responsible for IT.

Response: As discussed previously, we believe it is important that ACOs retain the flexibility to establish processes that are best suited to their own practices and patient populations. Thus, consistent with the requirements under section 1899(b)(2)(G) of the Act, Shared Savings Program, we will require that ACOs provide documentation in their applications describing their processes to internally report on quality and cost measures in order to be eligible to participate in the Shared Savings Program.

Comment: Some comments expressed concerns that, in rural settings, hospitals will not be able to address, achieve, and implement quality measures for patients with specific chronic conditions and that use of these hospitals will interrupt the relationship between patients and their respective specialty provider that are participating in the Shared Savings Program.

Response: We believe that the Shared Savings Program provides new incentives for providers in rural areas to develop the means to report on cost and quality of their patients with chronic conditions in ways that benefit their patient population.

Final Decision: We will finalize our proposal that to be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement and periodically update its processes and infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics to enable the ACO to monitor, provide feedback, and evaluate ACO participant and ACO provider/supplier performance and to use these results to improve care and service over time. (§ 425.112).

d. Processes To Promote Coordination of Care

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.'' We explained in the proposed rule that coordination of care involves strategies to promote, improve, and assess integration and consistency of care across primary care physicians, specialists, and acute and post-acute providers and suppliers, including methods to manage care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist.

We also noted that the strategies employed by an ACO to optimize care coordination should not impede the ability of a beneficiary to seek care from providers that are not participating in the ACO, or place any restrictions that are not legally required on the exchange of medical records with providers who are not part of the ACO. We proposed to prohibit the ACO from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

In addition, the process to promote coordination of care includes the ACOs having systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations. We proposed that an individualized care plan be tailored to—(1) the beneficiary's health and psychosocial needs; (2) account for beneficiary preferences and values; and (3) identify community and other resources to support the beneficiary in following the plan. This plan would be voluntary for the beneficiary, privacy protected, and would not be shared with Medicare or the ACO governing body; it would solely be used by the patient and ACO providers/suppliers for care coordination. If applicable, and with beneficiary consent, the care plan could be shared with the caregiver, family, and others involved in the beneficiary's care. An ACO would have a process in place for developing, updating, and, as appropriate, sharing the beneficiary care plan with others involved in the beneficiary's care, and providing it in a format that is actionable by the beneficiary.

We requested comments on our proposal that ACOs be required to demonstrate the processes they have in place to use individualized care plans for targeted beneficiary populations in order to be eligible for the Shared Savings Program. We proposed that the individualized care plans should include identification of community and other resources to support the beneficiary in following the plan. We also stated that we believe that a process for integrating community resources into the ACO is an important part of patient-centeredness.

For purposes of the application to participate in the Shared Savings Program, we proposed that an ACO would be required to 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, their high-risk and multiple chronic condition patients. In addition, the ACO should describe additional target populations that would benefit from individualized care plans. We also proposed that ACOs describe how they will partner with community stakeholders as part of their application. ACOs that have a stakeholder organization serving on their governing body would be deemed to have satisfied this requirement. We requested comment on these recommendations.

Comment: Comments received acknowledged 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 while other comments suggested that the proposed rule anticipated a level of functional health information exchange and technology adoption that may be too aggressive for deployment in January 2012.

Response: We agree that ACOs should coordinate care between all types of providers and across all services. We also agree that health information exchanges are of the utmost importance for both effective coordination of care activities and the success of the Shared Savings Program. We understand that there will be variable ability among ACOs to adopt the appropriate health information exchange technologies, but underscore the importance of robust health information exchange tools in effective care coordination. Additionally, as discussed in the Agreement section of this regulation, we will allow for two start dates in the first year of the agreement period. These additional start dates will provide an ''on ramp'' for all ACOs to get the appropriate health information exchanges in place before they enter the program.

Comment: Commenters supported our proposal to require an ACO to 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, their high-risk and multiple chronic condition patients. Several comments recommended that CMS make a stronger case for the need to integrate community resources into the individualized care plans by requiring that ACOs have a contractual agreement in place with community-based organizations.

Response: Although we agree with comments that the integration of community resources into the individualized care plans is important to the concept of patient-centeredness, we also believe it is important to afford ACOs the flexibility to accomplish this requirement in a manner that is most suited to their patient population.

Final Decision: We will finalize our proposal requiring ACOs to define their care coordination processes across and among primary care physicians, specialists, and acute and post acute providers. The ACO must also define its methods to manage care throughout an episode of care and during its transitions. The ACO must submit a description of its individualized care program as part of its application along with a sample care plan and explain how this program is used to promote improved outcomes for, at a minimum, their high-risk and multiple chronic condition patients. The ACO should also describe additional target populations that would benefit from individualized care plans. In addition, we will finalize our proposal that ACOs describe how they will partner with community stakeholders as part of their application. ACOs that have stakeholder organizations serving on their governing body will be deemed to have satisfied this requirement. (§ 425.112).

6. Overlap With Other CMS Shared Savings Initiatives

a. Duplication in Participation in Medicare Shared Savings Programs

The statute includes a provision that precludes duplication in participation in initiatives involving shared savings. Section 1899 of the Act states that providers of services or suppliers that participate in certain programs are not eligible to participate in the Shared Savings Program. Section 1899(b)(4) of the Act states these exclusions are ''(A) A model tested or expanded under section 1115A [the Innovation Center] that involves shared savings under this title or any other program or demonstration project that involves such shared savings; (B) The independence at home medical practice pilot program under section 1866E.''

In the proposed rule, we identified several programs or demonstrations that we believed included a shared savings component and would be considered duplicative. Specifically, we identified the Independence at Home Medical Practice Demonstration program, Medicare Health Care Quality (MHCQ) Demonstration Programs, Multipayer Advanced Primary Care Practice (MAPCP) demonstration, and the PGP Transition Demonstration. We also recognized that additional programs, demonstrations, or models with a shared savings component may be introduced in the Medicare program in the future. We recommended that interested parties check our Web site for an updated list.

We further noted that the prohibition against duplication in participation in initiatives involving shared savings applies only to programs that involve shared savings under Medicare. Providers and suppliers wishing to participate in the Shared Savings Program would not be prohibited from participating if they are also participating in demonstrations and initiatives established by the Affordable Care Act that do not involve Medicare patients or do not involve shared savings, such as State initiatives to provide health homes for Medicaid enrollees with chronic conditions as authorized under section 2703 of the Affordable Care Act.

As we explained in the proposed rule, we believe a principal reason underlying the prohibition against participation in multiple initiatives involving shared savings is to prevent a provider or supplier from being rewarded twice for achieving savings in the cost of care provided to the same beneficiary. Therefore, to ensure that a provider or supplier is rewarded only once with shared savings for the care of a beneficiary, an ACO participant may not also participate in another Medicare program or demonstration involving shared savings. However, in order to maintain as much flexibility as possible for ACO providers/suppliers to participate concurrently in multiple CMS initiatives involving shared savings, we do not believe it is appropriate to extend this prohibition to individual providers and suppliers. Accordingly, an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program under one ACO participant TIN and another shared savings program under a different non-ACO participant TIN if the patient population is unique to each program.

Finally, we proposed a process for ensuring that savings associated with beneficiaries assigned to an ACO participating in the Shared Savings Program are not duplicated by savings earned in another Medicare program or demonstration involving shared savings. If such a program assigns beneficiaries based upon the TINs of health care providers from whom they receive care, we proposed to compare the participating TINs in the program or demonstration with those participating in the Shared Savings Program to ensure that TINs used for beneficiary assignment to an ACO participating in the Shared Savings Program are unique and that beneficiaries are assigned to only one shared savings program. If the other program or demonstration involving shared savings does not assign beneficiaries based upon the TINs of the health care providers from whom they receive care, but uses an alternate beneficiary assignment methodology, we proposed working with the developers of the respective demonstrations and initiatives to devise an appropriate method to ensure no duplication in shared savings payment. We proposed that applications to the Shared Savings Program that include TINs that are already participating in another program or demonstration involving shared savings would be rejected.

Comment: Commenters generally requested clarification on what programs and demonstrations would be considered overlapping and disqualifying for participating in the Shared Savings Program. Some commenters asked CMS to confirm that initiatives such as the New Jersey gain sharing demonstration are not considered to overlap with the Shared Savings Program. Another commenter asked CMS for an official opinion whether the MHCQ demonstrations, specifically, the Indiana Health Information Exchange (IHIE) demonstration and the North Carolina Community Care Network, and an ACO could coexist and, if so, how CMS would calculate the shared savings.

Several commenters requested that CMS remove the MAPCP demonstration from the initiatives in which ACOs may not participate pointing out that the demonstration is not for shared savings, but rather one that is restricted to explicit payment for care coordination services to medical/health care homes. One commenter stated that it is possible to account for costs and payments in MAPCP and in an ACO so that CMS does not reward the same savings more than once.

Some commenters asked CMS to provide guidance on whether participation in other value-based purchasing initiatives or demonstrations that do not involve shared savings, such as the Community-Based Care Transitions Programs, Hospital Value-Based Purchasing Programs, bundled payment programs, Maryland's all-payer waiver, or other Innovation Center initiatives, would overlap with the Shared Savings Program. Other commenters wondered whether organizations participating in State shared savings initiatives involving Medicaid or dually eligible beneficiaries would be ineligible to participate in the Shared Savings Program. One commenter requested a comprehensive list of initiatives involving shared savings for which there would be overlap.

Response: We have determined there are several ongoing demonstrations involving shared savings that would be considered overlapping. We have determined that currently two of the MHCQ demonstration programs, the IHIE and North Carolina Community Care Network (NCCCN), involve shared savings payments for a Medicare population, therefore, providers and suppliers who participate in the IHIE and NCCCN will not be permitted to also participate in the Medicare Shared Savings Program. However, once a Medicare enrolled TIN completes its participation in the IHIE or NCCCN, it may apply for the Shared Savings Program and would no longer be prohibited from participation because of duplication.

At the time of publication of the proposed rule, the MAPCP demonstration offered several different payment arrangements to participating providers. Since then, we selected the States of Maine, Vermont, New York, Rhode Island, Pennsylvania, North Carolina, Michigan, and Minnesota for the MAPCP Demonstration. To the extent that any of the participating providers have chosen a shared savings arrangement, participation in both MAPCP and the Shared Savings Program will be prohibited. MAPCP participants who do not have shared savings arrangements under the demonstration would not be prohibited from participating in the Shared Savings Program.

Subsequent to publication of the proposed rule, we have determined that the Care Management for High-Cost Beneficiaries Demonstrations authorized by 42 U.S.C. 1395b–1 is also a shared savings program, as well as the Pioneer ACO Model.

After due consideration, we have determined that providers would be able to participate in both the Medicare Shared Savings Program and programs that focus on the integration of the Medicare and Medicaid programs for dually eligible individuals, specifically, State initiatives to integrate care for dually eligible individuals announced recently by the Medicare-Medicaid Coordination Office in partnership with the Innovation Center. Due to the unique design of these demonstrations as well as the relationship of States with providers in the Medicaid program, it is not necessary or reasonable to prohibit involvement in both programs. However, we will work closely with providers and States to prevent duplication of payment. Furthermore, we have also determined that demonstrations that do not involve shared savings, such as the New Jersey gain sharing demonstration and others would not be considered overlapping for purposes of participation in the Shared Savings Program.

Comment: We received several comments regarding transitions from demonstrations to the Shared Savings Program. A member organization of the IHIE thanked CMS for acknowledging the demonstration as a worthwhile project. The commenter wrote that it would be counterproductive to halt the MHCQ demonstration after substantial investment in that program to make it a success, especially since the goals of the program and ACOs are consistent.

One commenter indicated that the potential transition from the IHIE demonstration to the Shared Savings Program may be difficult because of the asynchronous performance years under the two programs. Several other commenters wrote in support of transitioning North Carolina's 646 demonstration program into an ACO and reported that Community Care of North Carolina is already taking steps to establish a North Carolina Accountable Care Collaborative. A commenter suggested that CMS clarify at what point a Medicare-enrolled TIN previously involved in another shared savings would be eligible for participation in an ACO under the Shared Savings Program.

Response: We recognize that our initiatives may have different lengths of agreement periods or different start and end dates. In the Shared Savings Program, we sought to align with many programs that function on a calendar year basis, such as the Physician Quality Reporting System (PQRS). We do not believe this proposal should disrupt ongoing participation in other shared savings initiatives, and we encourage participants in ongoing demonstrations to complete the term of their agreement before entering the Shared Savings Program. We recognize that not all programs and demonstrations operate on a calendar year basis and that, as a result, there may be some providers and suppliers who will have gaps in time from the end of one program or demonstration to the beginning of participation in another. An entity must have terminated its involvement with another shared savings program prior to participation in the ACO Shared Savings Program. After an organization with a Medicare-enrolled TIN concludes an overlapping shared savings demonstration, its application to the Shared Savings Program would not be denied on the basis of duplication.

Comment: Several commenters suggested that the restriction against participation in multiple initiatives involving shared savings would potentially stifle creation of other leading-edge initiatives that are well-aligned with best practices for patient quality of care. One commenter stated that CMS should not deter ACOs from investing in other delivery system innovations such as patient-centered medical homes and healthcare innovation zones that share objectives. One commenter asked if an ACO might not receive all of the potential savings if the organization or the same patients are also participating in another shared savings program. If so, the commenter

believed that this would be a significant deterrent to participation because an organization would have to decide between Shared Savings Program and other Innovation Center initiatives. Another commenter encouraged CMS, if it finds that the statute is creating too many barriers to entry for interested providers and suppliers, to approach Congress to request that the restriction be eased. One commenter suggested that the Secretary should consider a mechanism to provide waivers to organizations that are especially well-suited to innovation in care delivery and that could provide substantial benefit to CMS to permit participation in multiple projects or trials. A commenter questioned if there are multiple TINs in a system, whether one TIN can participate in the Shared Savings Program and another in an Innovation Center program for example, the independence at home project, the State option to provide health homes and the use of community health teams. Several commenters recommended that for groups with multiple companies or subsidiaries, the separate divisions should be permitted to simultaneously seek ACO contracts.

One commenter suggested that to ensure broad participation by Medicare providers and suppliers, CMS should read section 1899(b)(4) of the Act more narrowly than CMS has proposed. At a minimum, CMS should only restrict ACO participants from also participating in a program or demonstration project that is primarily intended to share savings. CMS should not read section 1899(b)(4) of the Act to preclude a provider or supplier's participation in an ACO by virtue of the fact that the provider or supplier is also participating in another program that incidentally makes payments based on cost reductions.

Another commenter stated that if a particular ACO provider/supplier only bills Medicare under one TIN, as is the case for some physician groups and other suppliers, and the TIN is an ACO participant, that individual ACO provider/supplier would be unable to participate in any other initiatives involving shared savings. This commenter suggested the prohibition would prevent such a group from successfully coordinating the care of Medicare beneficiaries who are not assigned to the ACO under the Shared Savings Program but are assigned to an organization under another shared savings model.

Response: We believe there is opportunity for providers and suppliers to participate in multiple complementary initiatives. However, the statute clearly states that a provider that participates in any other program or demonstration project that involves shared savings under Medicare is ineligible to participate in an ACO under the Shared Savings Program. We believe our operational definition of an ACO as a collection of Medicare enrolled TINs, combined with our assignment methodology, discussed in section II.E of this final rule, helps ensure a unique patient population to an ACO on the basis of services billed by the ACO participant TINs. We recognize that health systems may be comprised of multiple TINs that bill Medicare. It may be appropriate for some of those TINs to apply to participate in the Shared Savings Program while others do not. We believe organizations should have flexibility to determine what TINs join together to form an ACO.

To ensure that a provider or supplier is rewarded only once with shared savings for the care of a beneficiary, we proposed that an ACO participant TIN may not also participate in another Medicare program or demonstration involving shared savings. However, in order to maintain as much flexibility as possible for ACO providers/suppliers to participate concurrently in multiple CMS initiatives involving shared savings, we do not believe it is appropriate to extend this prohibition to individual providers and suppliers. Accordingly, an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program and another shared savings program if the patient population is unique to each program and if none of the relevant Medicare-enrolled TINs participate in both programs. For example, an ACO practitioner participating in the Shared Savings Program under an ACO participant practice TIN could also participate in the Independence at Home Demonstration under a non-ACO participant TIN since there would be no duplication in beneficiary assignment; and therefore, no duplication in shared savings.

We believe our proposal identifying ongoing CMS initiatives that involve shared savings meets both the letter and spirit of the statutory prohibition against duplication of participation in initiatives involving shared savings. Furthermore, we do not believe the fact that the stated goal of a particular program is something other than to achieve shared savings lessens the potential for duplication in payment for the same beneficiaries or changes the applicability of the statutory prohibition against duplicative participation when the incentive for participation in the other program is the provision of shared savings. As noted previously, in developing our proposed policy, we carefully considered currently implemented programs and sought to provide as much flexibility as possible to potential Shared Savings Program participants while also ensuring there is no duplication in payments for savings achieved for the same Medicare beneficiaries.

Further, we disagree with the conclusion that the prohibition against participating in duplicative initiatives involving shared savings would prevent a practice or an individual practitioner that bills under a single TIN from successfully coordinating the care of Medicare beneficiaries who are not assigned to the ACO under the Shared Savings Program but are assigned to an organization under another shared savings model. We believe that the Shared Savings Program assignment methodology, described in detail in section II.E of this final rule, provides an incentive for participating providers and suppliers to redesign care delivery to all their Medicare FFS beneficiaries.

Finally, we note, as explained in section II.E of this final rule, that certain Shared Savings Program ACO participants have the opportunity to participate in more than one Medicare Shared Savings Program ACO, as long as assignment of beneficiaries is not dependent on the ACO participant TIN. We believe that participation in more than one ACO within the Shared Savings Program is separate and distinct from participating in multiple Medicare shared savings initiatives, and therefore would not be subject to the statutory prohibition.

Comment: Many commenters suggested that CMS allow participation in multiple initiatives involving shared savings provided that such participation does not result in double counting achieved savings and providing that the same patients are not assigned to both demonstrations, for example, some large health systems suggested they should be able to participate in multiple programs so long as CMS ensures they are not being paid twice for the same care to the same patient. A commenter encouraged CMS to consider ways to prevent duplicative payments based on the beneficiary identification so that a provider or supplier to whom a particular beneficiary is assigned is only rewarded once for that beneficiary.

Response: We believe our proposed methodology ensures no duplication in payment while adequately allowing provider flexibility. Further, the law states that a provider may not

participate in this program if they are already participating in another shared savings program, so for purposes of determining eligibility to participate in the Shared Savings Program, we will review the ACO participant TINs submitted on the application of a prospective ACO and determine whether or not those TINs are already participating in another shared savings program. Applications that have such an overlap will be rejected. Furthermore, despite this precaution, because assignment methodologies may differ from program to program, as noted previously in the case of the Pioneer ACO Model, we will work with other initiatives involving shared savings and demonstrations to prevent duplicative payments based on beneficiary identification where necessary. We would note that while participation in some demonstrations, for example, the Bundled Payment for Care Improvement Initiative, would not exclude ACO participants from participating in the Shared Savings Program, it is our intention to ensure duplicative payments are not being made within the design of the demonstration.

Comment: A few commenters requested clarification that this prohibition does not apply to providers and suppliers upon whom assignment cannot be based or to non-Medicare enrolled participants.

Response: We disagree that ACO participants upon whom assignment is not based may participate in multiple initiatives involving shared savings. We read section 1899(b)(4) of the Act to direct us to ensure that ACO participants are not also participating in another initiative involving shared savings. Furthermore, such an interpretation would be inconsistent with the intent of the law, which is to avoid duplicate incentive payments across initiatives. However, within the Shared Savings Program itself, we are able to prevent duplicate payments by ensuring unique assignment to each ACO. As described in section II.E of this final rule, ACO participants upon whom assignment is not based would have the opportunity to participate in more than one Medicare Shared Savings Program ACO, that is, they would not be required to be exclusive to a single Medicare Shared Savings Program ACO. In response to specific requests for clarification, we note that these final rules apply only to Medicare enrolled ACO participants and ACO providers/suppliers. They do not apply to providers and suppliers that are not enrolled in Medicare.

Comment: A commenter questioned whether a provider or supplier, for example, a pharmacy, could fill prescriptions and provide health screenings for more than one ACO.

Response: We appreciate this question; however, we are unclear exactly what the commenter is asking. That is, it is unclear whether the commenter is wondering whether they can participate in more than one Medicare ACO or whether they are asking if, once in an ACO, the services they render would be limited to ACO assigned beneficiaries. We stress that the Medicare Shared Savings Program is not a managed care program and as such does not require lock in of beneficiaries nor does it require a participating provider or supplier to reassign their billing to the ACO or render services only on behalf of the ACO or only to beneficiaries assigned to the ACO. Medicare enrolled providers and suppliers that are participating in an ACO or whose beneficiaries are assigned to an ACO would continue to care for their beneficiaries and bill Medicare for services rendered under FFS as usual.

However, for purposes of participation in the program, as described in more detail in section II.E of this final rule, ACO participants upon whom assignment is based must be exclusive to a single ACO. So providers and suppliers who do not bill for primary care services and upon whom assignment is not based, including pharmacies, would have the opportunity to participate in multiple ACOs in the Shared Savings Program.

Final Decision: We have identified several current initiatives in which ACO participants receive shared savings such that they would be prohibited from participation in the Shared Savings Program: Independence at Home, the MHCQ IHIE and NCCCN demonstrations, MAPCP arrangements involving shared savings, PGP Transition demonstration, the Care Management for High-Cost Beneficiaries Demonstrations, and the Pioneer ACO Model through the Innovation Center. We recognize, however, that there may be other demonstrations or programs that will be implemented or expanded as a result of the Affordable Care Act, some in the near future. We will update our list of duplicative shared savings efforts periodically to inform prospective Shared Savings Program participants and as part of the application.

Additionally, we are finalizing our proposal to implement a process for ensuring that savings associated with beneficiaries assigned to an ACO participating in the Shared Savings Program are not duplicated by savings earned in another Medicare program or demonstration involving shared savings. Specifically, applications for participation in the Shared Savings Program will be reviewed carefully to assess for overlapping TINs. TINs that are already participating in another Medicare program or demonstration involving shared savings will be prohibited from participating in the Medicare Shared Savings Program. An ACO application that contains TINs that are already participating in another Medicare program or demonstration involving shared savings will be rejected.

If the other program or demonstration involving shared savings does not assign beneficiaries based upon the TINs of the health care providers from whom they receive care, but uses an alternate beneficiary assignment methodology, we will work with the developers of the respective demonstrations and initiatives to devise an appropriate method to ensure no duplication in shared savings payment. For example, billing TINs who are participating in the Pioneer ACO Model would be prohibited from also participating in the Shared Savings Program. Additionally, since the Pioneer ACO Model may begin before the Shared Savings Program and assigns beneficiaries prospectively, we will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both (§ 425.114).

b. Transition of the Physician Group Practice (PGP) Demonstration Sites Into the Shared Savings Program

The PGP demonstration, authorized under section 1866A of the Act, serves as a model for many aspects of the Shared Savings Program. The Affordable Care Act provided authority for the Secretary to extend the PGP demonstration. On August 8, 2011 we announced the PGP Transition Demonstration which will follow many of the same parameters from the original PGP Demonstration, with some modifications. The modifications include: shifting spending benchmarks to the national rather than regional level, aligning beneficiaries first with primary care physicians (PCPs) and then specialists, and implementing a patient experience of care survey. All 10 PGP demonstration participants have agreed to participate in the PGP Transition Demonstration.

As discussed previously, consistent with 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 demonstration project that involves shared savings, such as the PGP

demonstration. Thus, the PGP sites will not be permitted to participate concurrently in the Shared Savings Program. Since assignment methodologies are similar between the Shared Savings Program and the PGP demonstration, we will provide for unique assignment of beneficiaries by ensuring there is no overlap in participating Medicare-enrolled TINs as mentioned previously.

In the proposed rule, we discussed an appropriate transition in the event that a PGP site decides to apply for participation to the Shared Savings Program. We proposed to give the site the opportunity to complete a condensed application form. The condensed application form would require the applicant to provide the information that is 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 and, if necessary, to update any information contained in its application for the PGP demonstration that is also required on the standard Shared Savings Program application.

Comment: One commenter noted they thought that several innovative health care systems such as PGP demo sites have indicated that they will forego applying to the Shared Savings Program but would instead ''apply for funding'' through the Innovation Center.

Response: We recognize there are many opportunities for organizations to participate in our programs involving shared savings as well as other Affordable Care Act demonstrations. We are pleased that all 10 of the original PGP demonstration sites have contracted to participate in the PGP Transition Demonstration which implements many of the same policies as the Shared Savings Program.

Final Decision: We are finalizing our proposals without change (§ 425.202).

c. Overlap With the Center for Medicare & Medicaid Innovation (Innovation Center) Shared Savings Models

Section 1899(i) of the Act gives the Secretary the authority under the Shared Savings Program to use other payment models determined to be appropriate, including partial capitation and any additional payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under Medicare. The purpose of the Innovation Center, established in section 1115A of the Act, is to test innovative payment and service delivery models to reduce expenditures under Medicare, Medicaid, and the CHIP, while preserving or enhancing the quality of care furnished to individuals under these programs. Preparations are currently underway to develop this capability. Within the Innovation Center, it may be possible to test different payment models, provide assistance to groups of providers and suppliers that wish to develop into an ACO, or enhance our understanding of different benchmarking methods. As the Innovation Center gains experience with different ACO payment models, we can use proven methods to enhance and improve the Shared Savings Program over time.

The Innovation Center has recently implemented or is exploring several ACO-related initiatives:

- Pioneer ACO Model—announced in a May 17, 2011 Request for Application.
- Accelerated development learning sessions (ADLS)—to provide the executive leadership teams from existing or emerging ACO entities the opportunity to learn about essential ACO functions and ways to build capacity needed to achieve better care, better health, and lower costs through improvement.
- Advance Payment Model—Subsequent to the publication of the proposed rule, the Innovation Center sought comment on providing an advance on the shared savings ACOs are expected to earn as a monthly payment for each preliminarily prospectively assigned Medicare beneficiary.

As discussed previously, section 1899(b)(4) of the Act restricts providers of services and suppliers from participating in both the Shared Savings Program and other Medicare shared savings programs and demonstrations. We intend to coordinate our efforts to ensure that there is no duplication of participation in shared savings programs through provider or supplier participation in both the Shared Savings Program and any Medicare shared savings models tested by the Innovation Center. Similarly, we will also take steps to ensure there is a methodology to avoid duplication of shared savings payments for beneficiaries aligned with providers and suppliers in both the Shared Savings Program and any current or future models tested by the Innovation Center.

Further, we are looking forward to applying lessons learned in the Pioneer ACO Model that can help inform changes to the Shared Savings Program over time.

Comment: Many commenters were supportive of the purpose of the Innovation Center, the concept of the Advance Payment Model, and the Pioneer Model ACO demonstration. Commenters applauded the use of lessons learned in the Pioneer program to inform the Shared Savings Program and noted that the Pioneer model may effectively test innovative models that may be more effective for certain types of providers. Some commenters made specific suggestions for improvement of the Pioneer model.

Response: We appreciate the feedback, and have passed specific suggestions for improvements to the Pioneer ACO Model on to the Innovation Center.

Comment: A number of commenters expressed concerns about the upfront costs to participate and urged CMS to address the need for startup funding in the final rule.

Many commenters were generally supportive of providing advanced payments to ACOs through the Innovation Center. These commenters suggested that advance payments would make program participation more attractive to many ACOs, particularly those comprised of networks of smaller practices, providers that operate on small margins, or hospitals in specific regions of the country. Several commenters suggested that financial support from a program such as the Advance Payment Models alone may be insufficient to allay the very high startup costs for ACOs. Some suggested direct capital support was necessary and suggested alternatives to the Advance Payment Model. Some commenters asked for clarification or offered suggestions on specific aspects of the initiative, such as the structure of the incentive or eligibility criteria.

Many urged CMS to provide upfront capital support to ACOs to defray start-up and operational expenses and to encourage participation, and some suggested that based on PGP data, ACOs may require more than three years to recoup their start up investment. Several commenters concurred with the need for robust health information technology (HIT) in ACOs but stated that acquisition costs create a substantial barrier to physician ACOs. Numerous commenters urged CMS to create additional ways to help finance physicians' acquisition of HIT. Several explained that shared savings alone will not assist practices with upfront costs nor provide assurance that they will recover their initial investments and that, as a result, transitional models are needed. A few commenters noted that providers should not have to divert resources to two similar initiatives (for example, electronic health records incentives and shared savings) with only technical differences. Groups identified by commenters that may be

especially challenged by the upfront costs of ACO formation and operations include: Private primary care practitioners, small to medium sized physician practices, small ACOs, MAPCP demonstration programs, minority physicians and physicians who see minority patients, safety net providers (that is, RHCs, CAHs, FQHCs, community-funded safety net clinics (CSNCs)), rural providers (that is, Method II CAHs, rural PPS hospitals designated as rural referral centers, sole community hospitals or Medicare dependent hospitals), and rural primary care providers. A few commenters suggested that CMS offer special funding or access to capital through grants or no-interest loans for ACOs formed by rural and safety-net providers, or other providers, such as home health or hospice providers, to enhance participation of these groups in the Shared Savings Program. A commenter suggested that CMS offer a rural primary care provider incentive, such as an enhanced FFS payment or other payment methods (for example, partial capitation), for joining a Medicare ACO to help fund the infrastructure requirements of a Medicare ACO, buffer risk, and stimulate further participation.

Some commenters made specific suggestions for offsetting costs to the ACO, for example, a number of comments recommended that the final rule provide an additional financial incentive for the collection and reporting of patient satisfaction data or other quality data.

On the other hand, some commenters noted that many high quality organizations are likely to have already made the capital investments to achieve high quality and efficient care delivery, and are therefore poised to become ACOs.

Response: We recognize that a real commitment to improving care processes for Medicare beneficiaries will require financial investment on the part of the ACO, ACO participants, and ACO providers/suppliers. The Shared Savings Program is designed to provide an incentive for ACOs demonstrating high quality and improved efficiencies. We have passed along comments related to Advance Payment to our colleagues in the Innovation Center.

In this final rule, we have made significant changes to reduce burden on participants and improve the opportunity to share in savings. In section II.F. of this final rule, we note our intent to provide funding for the patient experience of care survey for 2012 and 2013, providing early adopters with additional upfront assistance. In section II.G (shared savings/losses) of this final rule, we describe changes to the financial model that benefit Shared Savings Program participants such as removal of the 25 percent withhold, removal of the net 2 percent requirement so that ACOs may share from first dollar savings once the MSR is overcome, and an increase to the shared savings cap. Additionally, in response to comments, we are reducing the claims run out period from 6 to 3 months, allowing for earlier payment of shared savings. Finally, in section II.C. (Agreement) of this final rule, we discuss lengthening the agreement period for early adopters. Moreover, as noted, the Innovation Center is considering an Advance Payment model for certain ACOs, which would test whether pre-paying a portion of future shared savings could increase participation in the Shared Savings Program.

Finally, we note there are also other public and private options to offset start up costs such as financing arrangements, grants from non-profit and existing government sources, as well as savings from non-Medicare patient populations. Other CMS initiatives, such as the EHR Incentive Program, provide incentives for HIT adoption. Potential participants will want to consider all options available.

Comment: Several commenters suggested that CMS provide technical assistance to certain ACOs such as those comprised of safety net providers, or physician-only ACOs, or to ACOs in general.

Response: In addition to ongoing technical assistance provided for specific program activities, such as quality measures reporting, we will consider ways in which additional assistance can be provided to Shared Savings Program ACOs. We note that the Innovation Center has held several well-received ADLS sessions designed to provide the executive leadership teams from existing or emerging ACO entities the opportunity to learn about essential ACO functions and ways to build capacity needed to achieve better care, better health, and lower costs through improvement. We will also explore other opportunities to assist Shared Savings Program ACOs.

Final Decision: We are finalizing our proposal to exclude Pioneer ACO Model participants from participation in the Shared Savings Program. Additionally, since the Pioneer ACO Model may begin before the Shared Savings Program and will and assign beneficiaries prospectively, we will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both (§ 425.114).

C. Establishing the Agreement With the Secretary

1. Options for Start Date of the Performance Year

Section 1899(a)(1) of the Act requires the Shared Savings Program to be established ''not later than January 1, 2012''. This final rule establishes the Shared Savings Program. We will start accepting applications from prospective ACOs shortly after January 1, 2012. For information on the application process, please see our Notice of Intent which will appear shortly after publication of this final rule at *https://www.cms.gov/sharedsavingsprogram/*.

Section 1899(b)(2)(B) of the Act provides that an ''ACO shall enter into an agreement with the Secretary to participate in the [Shared Savings Program] for no less than a 3-year period * * *'' Section 1899(d)(1) of the Act provides that an ACO shall be eligible to receive shared savings payments for each ''year of the agreement period,'' if the ACO has met applicable quality performance standards and achieved the requisite savings. In establishing the requirement for a minimum 3-year agreement period, the statute does not prescribe a particular application period or specify a start date for ACO agreement periods.

In the proposed rule we considered several options for establishing the start date of the agreement period: annual start dates; semiannual start dates; rolling start dates; and delayed start dates. Adopting an annual application period and start date would create cohorts of ACO applicants, which would allow for more streamlined processes related to evaluation of applications, agreement renewals, and performance analysis, evaluation, and monitoring. However, given the short timeframe for implementation of the program and our desire to permit as many qualified ACOs as possible to participate in the first year, we also gave a great deal of consideration to alternative approaches that would provide flexibility to program applicants. For instance, we considered allowing applicants to apply throughout the course of the year as they become ready and we could review and approve applications and begin agreement periods on a rolling basis. We noted however that, if ACO agreements begin more often than once a year, beneficiaries could be assigned to two ACOs for an overlapping period. As discussed in section II.E.3. of this final rule, we proposed that beneficiaries

would be assigned to ACOs based upon where they receive the plurality of their primary care services. Since the physician associated with the plurality of a beneficiary's primary care services could vary from year to year, having multiple start dates could result in a beneficiary being assigned to multiple ACOs for an overlapping period. This scenario would result in confusion for beneficiaries and the potential for duplicate shared savings payments for care provided to a single beneficiary. Additionally, problems with patient assignment may cause unintended consequences for per capita costs, making it difficult to make comparisons of one ACO's performance to another that has a different start date.

After evaluating various options for start dates, we proposed to establish an application process with an annual application period during which a cohort of ACOs would be evaluated for eligibility to participate in the Shared Savings Program. We further proposed that the performance years would be based on the calendar year to be consistent with most CMS payment and quality incentive program cycles. Specifically, we proposed that: (1) ACO applications must be submitted by a deadline established by us; (2) we would review the applications and approve those from eligible organizations prior to the end of the calendar year; (3) the term of the participation agreement (''agreement period'') would begin on the January 1 following approval of an application; and (4) the ACO's performance years under the agreement would begin on January 1 of each year during the agreement period. Given our concern regarding the short time frame for implementing the Shared Savings Program in the first year of the program, we solicited comment on any alternatives to a January 1 start date for the first year of the Shared Savings Program, such as an additional start date of July 1, and allowing the term of the agreement for ACOs with a July 1, 2012 start date to be increased to 3.5 years. Under this example, the first performance ''year'' of the agreement would be defined as 18 months in order that all of the agreement periods would synchronize with ACOs entering the program on January 1, 2013. We proposed that if adopted, this alternative would only be available in the first year of the program and for all subsequent years applications would be reviewed and accepted prior to the beginning of the applicable calendar year and the term of all subsequent agreements would be for 3 years.

Comment: We received several comments that expressed concerns about the feasibility of a January 1, 2012 start date. Commenters were concerned about the ability of potential ACOs to organize, complete, and submit an application in time to be accepted into the first cohort as well as our ability to effectively review applications by January 1, 2012. Comments suggested that only well organized and larger integrated health care systems would be able to meet the January 1, 2012 start date. Alternatively, comments suggested that the January 1 start date would preclude most small and rural health care systems from being able to participate in the Shared Savings Program. The majority of comments requested a delayed start date or offered support for a July 1 start date for the first year of the program. There were also some comments that requested a 1 or 2 year delay in the start date of the program to allow prospective ACOs the opportunity to build their infrastructure. There were a few comments that requested that we accept applications on a ''rolling'' basis, allowing greater flexibility for the first year.

Response: We agree with the comments requesting additional flexibility in the start date of the Shared Savings Program. Therefore, based upon public comment, we will provide for two application periods for the first year of the Shared Savings Program whereby we will accept applications for an April 1, 2012 or July 1, 2012 start date. All ACOs that start in 2012 will have agreement periods that terminate at the end of 2015. We will provide sub-regulatory guidance to ACOs on the deadlines by which applications must be received in order to be considered for each respective start date.

We summarize the application of our final policy as follows:

ACO starts April 1, 2012: First performance year is 21 months, ending on December 31, 2013. Agreement period is 3 performance years, ending on December 31, 2015.

ACO starts July 1, 2012: First performance year is 18 months, ending on December 31, 2013. Agreement period is 3 performance years, ending on December 31, 2015.

Under this final rule, ACOs will begin receiving data immediately upon entry to the program (historical and quarterly aggregate reports along with rolling information on their preliminary prospective assigned beneficiary population as described in section II.D. of this final rule). After completing its first performance year, the ACO will be evaluated on its performance on the ACO quality metrics and a shared savings payment will be calculated. All ACOs will be eligible to receive the PQRS incentive payments for each calendar year in which they fully and completely report the Group Practice Reporting Option (GPRO) measures, regardless of their start date. This will provide ACOs that join the program in April or July 2012 with some working capital in advance of the completion of the first ACO performance year, regardless of their ability to generate shared savings.

We believe this approach fulfills several desirable goals for the program including: (1) Establishment of the program by January 1, 2012; (2) flexibility for newly formed ACOs to apply when ready; (3) a partial year on-ramp for ACOs to gain experience with understanding the assigned population through receipt of data reports and to gain experience in reporting measures using the PQRS GPRO tool before entering into a period of performance assessment; and (4) assurance that no beneficiary will be double-counted for purposes of establishing ACO performance when there is more than one ACO in a geographic region.

Comment: We received several comments requesting that we expand the agreement period. The majority of the comments surrounding the agreement period specifically requested that the agreement period be expanded to 5 years. The general consensus among comments was that a 3-year agreement period is too short and highlights the fact that the significant capital costs and the need to marshal necessary resources (for example, information technology infrastructure and appropriate management and leadership personnel) make success, in terms of savings, difficult in the early years, if not the entire proposed 3 year term. Comments suggested a 3-year agreement period, combined with our proposal to prohibit future participation of underperforming ACOs or participants after the original term of the agreement has lapsed, works against the small and rural markets that do not have the necessary basics in place to the same extent as larger more integrated health care systems. Commenters stated that the proposed 3-year agreement period increases the risk of loss before any chance of reward is available.

Even those few comments that offered support for a 3-year agreement period recommended that ACOs should be able to withdraw from that agreement without penalty due to the challenges associated with realizing savings in a 3-year agreement.

Response: As discussed previously, and based upon the review of public

comments, we will extend the agreement period to include an extended agreement for those ACOs beginning on April 1, 2012 and July 1, 2012. We believe that extending the agreement period allows for those ACOs that are ready to begin their agreement on April 1, 2012 and July 1, 2012 will provide an on-ramp for organizations to gain experience with measures reporting and data evaluation in the early part of the program. As discussed in Section II.G. of this final rule, we are not finalizing our proposal to require a 25 percent withhold of any shared savings realized to offset any future losses or to be forfeited if an ACO fails to complete the terms of its agreement.

Final Decision: As specified in § 425.200, for the first year of the Shared Savings Program (CY 2012), ACOs will be afforded the flexibility to submit to begin participation in the program on April 1 (resulting in an agreement period of 3 performance years with the first performance year of the agreement consisting of 21 months) or July 1 (resulting in an agreement period of 3 years with the first performance year of the agreement consisting of 18 months). During all calendar years of the agreement period, including the partial year associated with both the April 1, 2012 and July 1, 2012 start dates, the eligible providers participating in an ACO that meets the quality performance standard but does not generate shareable savings will qualify for a PQRS incentive payment (as described in sections II.F. of this final rule and § 425.504).

2. Timing and Process for Evaluating Shared Savings

Section 1899(d)(1) of the Act provides that an ACO shall be eligible to receive shared savings payments for each year of the agreement period, if the ACO has met the quality performance standards established under section 1899(b)(3) of the Act and has achieved the required percent of savings below its benchmark. However, the statute is silent with respect to when the shared savings determination should be made. Potential ACOs have indicated that they need timely feedback on their performance in order to develop and implement improvements in care delivery. In developing our proposals, we were attentive to the importance of determining shared savings payments and providing feedback to ACOs on their performance in a timely manner while at the same time not sacrificing the accuracy needed to calculate per capita expenditures.

Our determination of an ACO's eligibility to receive a payment for shared savings will be based upon an analysis of the claims submitted by providers and suppliers for services and supplies furnished to beneficiaries assigned to the ACO. There is an inherent lag between when a service is performed and when a claim is submitted to us for payment. Additionally, there is also a time lag between when the claim is received by us and when the claim is paid.

From the perspective of the utilization and expenditure data that would be needed in order to determine an ACO's eligibility to receive shared savings and to provide performance feedback reports, the longer the claims run-out period, the more complete and accurate the utilization and expenditure data would be for any given year. Higher completion percentages are associated with longer run-out periods and thus would necessitate a longer delay before we could determine whether an ACO is eligible to receive shared savings and provide performance feedback. Conversely, a lower completion percentage would be associated with a shorter run-out period and thus a quicker turnaround for the shared savings determination and for the provision of performance feedback. Based upon historical trends, a 3-month run-out would result in a completion percentage of approximately 98.5 percent for physician services and 98 percent for Part A services. A 6-month run-out of claims data results in a completion percentage of approximately 99.5 percent for physician services and 99 percent for Part A services. Since neither a 3-month nor a 6-month run-out of claims data would offer complete calendar year utilization and expenditure data, we proposed to work with our Office of the Actuary to determine if the calculation of a completion percentage would be warranted. We proposed that if determined necessary, the completion percentage would be applied to ensure that the shared savings determination reflects the full costs of care furnished to assigned beneficiaries during a given calendar year. Thus, we must balance the need to use the most accurate and complete claims data as possible to determine shared savings with the need to provide timely feedback to ACOs participating in the Shared Savings Program. Additionally, regardless of whether we use a 3-month or 6-month claims run-out period, we are concerned that some claims (for example, high cost claims) may be filed after the claims run-out period which would affect the accuracy of the amount of the shared savings payment. We considered and sought comment on ways to address this issue, including applying an adjustment factor determined by CMS actuaries to account for incomplete claims, termination of the ACO's agreement in cases where the ACO has been found to be holding claims back, or attributing claims submitted after the run-out period to the following performance year.

We proposed using a 6-month claims run-out period to calculate the benchmark and per capita expenditures for the performance year. A 6-month claims run-out would allow for a slightly more accurate determination of the per capita expenditures associated with each respective ACO; however, it would also delay the computation of shared savings payments and the provision of feedback to participating ACOs. We also sought comment on whether there are additional considerations that might make a 3-month claims run-out more appropriate.

Comment: Most of the comments received on this proposal supported a 3-month claims run-out period. Several other comments focused on the fact that ACOs will require significant start up investments to provide adequate infrastructure. These comments suggest that the shorter the turnaround period for feedback on both quality metrics and shared savings reconciliation, the more likely that cash flow distortions would not be created and the better the opportunity that ACOs will be able to continue to operate. We received no comments that supported a 6-month claims run-out.

Response: As discussed previously, our initial analysis of this policy focused on balancing the need for timely feedback and the benefits of utilizing the most complete data in calculating both the quality metrics and the shared savings reconciliation. Based upon our review of the proposal and the input of public comments, we feel that the minimal increased accuracy associated with 6 months of claims run-out does not justify the additional delay in the provision of quality metrics feedback and shared savings reconciliation. We agree that ACOs should receive quality metric feedback as soon as possible so they can focus their activities on potential problem areas. Additionally, public comments have made it clear that a 3-month run-out of claims data, especially in the first year of the agreement, would aid in ensuring success for ACOs by allowing ACOs to offset the initial start up costs which would in turn allow the ACOs to remain financially viable. We agree with the comments that the decrease in the accuracy of the actual data between 6-

months of claims run-out and 3-months of claims run-out can be mitigated by the application of a completion percentage and should not delay the delivery of either the feedback on quality metrics or the reconciliation of any shared savings realized.

Final Decision: Based upon our review of the public comments received on the proposed policy, we are finalizing a policy, under § 425.602, § 425.604, and § 425.606 of using 3-months of claims run-out data, with the application of an appropriate completion percentage, to calculate the benchmark and per capita expenditures for the performance year. We will monitor ACO providers and suppliers for any deliberate delay in submission of claims that would result in an unusual increase in the claims incurred during the performance year, but submitted after, the 3 month run-out period immediately following each performance year, and as discussed in section II.H. of this final rule, will consider such deliberate behavior grounds for termination.

3. New Program Standards Established During the Agreement Period

In the proposed rule, we stated that as we continue to work with the stakeholder community and learn what methods and measures work most effectively for the Shared Savings Program, we would likely make changes and improvements to the Shared Savings Program over time. For example, we expect to integrate lessons learned from Innovation Center initiatives to shape and change the Shared Savings Program. Because we expect that these changes may occur on an ongoing basis, the question arises as to whether an ACO that has already committed to an agreement to participate in the Shared Savings Program should be subject to regulatory changes that become effective after the start of its agreement period.

In the proposed rule, we weighed the pros and cons of requiring an ACO to comply with changes in regulations that become effective before the expiration of its agreement period. We recognized that creating an environment in which the continued eligibility of existing program participants is uncertain could be detrimental to the success of the program and could deter program participation. Conversely, the ability to incorporate regulatory changes into the agreements with ACOs would facilitate the administration of the program because all ACOs would be subject to the requirements imposed under the current regulations, rather than different sets of requirements, depending upon what regulations were in effect in the year in which the ACO entered the program. Additionally, requiring ACOs to adhere to certain regulatory changes related to quality measures, program integrity issues, processes for quality management and patient engagement, and patient-centeredness criteria that are up to date with current clinical practice ensures that ACO activities keep pace with changes in clinical practices and developments in evidence-based medicine. We noted that it is not unprecedented for Medicare agreements to include a provision requiring that the agreement is subject to changes in laws and regulations. For example, the contracts with Medicare Advantage organizations contain such a clause. However, these contracts are for a term of 1 year, as opposed to 3 or more years. As a result, there are more frequent opportunities for these organizations to reassess whether they wish to continue to participate in the program in light of changes to the laws and regulations governing the program.

We proposed that ACOs would be subject to future changes in regulation with the exception of all of the following:

- Eligibility requirements concerning the structure and governance of ACOs.
- Calculation of sharing rate.
- Beneficiary assignment.

Thus, for example, ACOs would be subject to changes in regulation related to the quality performance standard. The language of the ACO agreement would be explicit to ensure that ACOs understand the dynamic nature of this part of the program and what specific programmatic changes would be incorporated into the agreement. We further proposed that in those instances where regulatory modifications effectuate changes in the processes associated with an ACO pertaining to design, delivery, quality of care, or planned shared savings distribution the ACO would be required to submit to us for review and approval, as a supplement to their original application, an explanation of how it will address key changes in processes resulting from these modifications. If an ACO failed to effectuate the changes needed to adhere to the regulatory modifications, we proposed that the ACO would be placed on a corrective action plan, and if after being given an opportunity to act upon the corrective action plan, the ACO still failed to come into compliance, it would be terminated from the program. For a more detailed discussion of the process for requiring and implementing a corrective action plan, please refer to the section II.H.5 of this final rule. We proposed that ACO participants would continue to be subject to all requirements applicable to FFS Medicare, such as routine CMS business operations updates and changes in FFS coverage criteria, as they may be amended from time to time.

Comment: The commenters did not support establishing new standards during the agreement period. Many comments suggested that in order to create the certainty required prior to ACOs making investments in population health management infrastructure, CMS should withdraw any proposals that will afford the agency the ability to alter the terms or requirements to participate in the program during an agreement period. Commenters requested that if standards are established during the agreement period, ACOs should be allowed to either voluntarily terminate their agreements without penalty or should be afforded protections against any changes that negatively affect the ACOs' ability to achieve their obligations under the agreement or that substantially alter the financial terms of their agreement. Other commenters specified that in those instances where standards are established during an agreement period, ACOs be afforded the opportunity to develop a real-time understanding of the new standards via a standard comment and response period. Finally, one commenter recommended that any program changes be introduced only at the start of a new agreement period.

Response: To ensure that ACO activities keep pace with the ever evolving developments in clinical practices and evidence-based medicine, it is important to retain the ability to make changes to the Shared Savings Program on an on-going basis. However, based upon our review of the public comments received on this policy, we agree with allowing an ACO the choice of whether to terminate its agreement without penalty when there are regulatory changes to the Shared Savings Program that impact the ability of the ACO to continue to participate. We believe this policy allows the program flexibility to improve over time while also providing a mechanism for ACOs to evaluate how regulatory changes impact their ability to continue participation in the program and to terminate their agreement without penalty if regulatory changes occur that will negatively impact the ACO.

Final Decision: Under § 425.212 we will finalize our proposal that ACOs be held responsible for all regulatory changes in policy, with the exception of: eligibility requirements concerning the structure and governance of ACOs, calculation of sharing rate, and

beneficiary assignment. However, we will modify our proposal to allow ACOs the flexibility to voluntarily terminate their agreement in those instances where regulatory standards are established during the agreement period which the ACO believes will impact the ability of the ACO to continue to participate in the Shared Savings Program.

4. Managing Significant Changes to the ACO During the Agreement Period

Aside from changes that may result from regulatory changes, the ACO itself may also experience significant changes within the course of its agreement period due to a variety of events, including the following:

- Deviations from the structure approved in the ACO's application, such as, if an ACO participant upon which assignment is based drops out of the program; changes in overall governing body composition or leadership; changes in ACO's eligibility to participate in the program, including changes to the key processes pertaining to the design, delivery and quality of care (such as processes for quality management and patient engagement and patient centeredness) as outlined in the ACO's application for acceptance into the program; or changes in planned distribution of shared savings.
- A material change, as defined in the proposed rule [76 FR 19527], in the ACO's provider/supplier composition, including the addition of ACO providers/suppliers.
- Government- or court-ordered ACO reorganization, OIG exclusion of the ACO, an ACO participant, or an ACO provider/supplier for any reason authorized by law; CMS revoking an ACO, ACO participant or ACO provider/supplier's Medicare billing privileges under 42 CFR § 424.535, for noncompliance with billing requirements or other prohibited conduct; or reorganization or conduct restrictions to resolve antitrust concerns.

Whenever an ACO reorganizes its structure, we must determine if the ACO remains eligible to participate in the Shared Savings Program. Under our proposal, we noted that since an ACO is admitted to the program based on the information contained in its application, adding ACO participants during the course of the agreement period may result in the ACO deviating from its approved application and could jeopardize its eligibility to participate in the program. We therefore proposed that the ACO may not add ACO participants during the course of the agreement. In order to maintain flexibility, however, we proposed that the ACO may remove ACO participants (TINs) or add or remove ACO providers/suppliers (NPIs). We requested comment on this proposal and how it might impact small or rural ACOs.

In addition, we proposed that ACOs must notify us at least 30 days prior to any ''significant change,'' which we defined as an event that causes the ACO to be unable to comply with the terms of the participation agreement due to (1) deviation from its approved application, such as a reorganization of the ACO's legal structure or other changes in eligibility; (2) a material change, which was defined in proposed § 425.14 to include ''significant changes'' as well as other changes that may affect ACO eligibility to participate in the program, including changes in governing body composition and the imposition of sanctions or other actions taken against the ACO by an accrediting organization or government organization, or (3) government or court-ordered reorganization as a result of fraud or antitrust concerns. We proposed that, in response to such a notification, we would make one of the following determinations:

- The ACO may continue to operate under the new structure with savings calculations for the performance year based upon the updated list of ACO participants and ACO providers/suppliers.
- The remaining ACO structure qualifies as an ACO but is so different from the initially approved ACO structure that the ACO must start over as a new ACO with a new agreement.
- The remaining ACO structure qualifies as an ACO but is materially different from the initially approved ACO structure because of the inclusion of additional ACO providers/suppliers that the ACO must obtain approval from a reviewing Antitrust Agency before it can continue in the program.
- The remaining ACO structure no longer meets the eligibility criteria for the program, and the ACO would no longer be able to participate in the program, for example, if the ACO's assigned population falls below 5,000 during an performance year as discussed in section II.B. of this final rule.
- CMS and the ACO may mutually decide to terminate the agreement.

Comment: The proposals surrounding the management of significant changes to the ACO during the agreement period were the most commented upon proposals in section II.C. of the proposed rule. All comments received suggested that not being able to add ACO participants during the agreement period runs counter to the idea of encouraging more integrated models and thus greater coordination of care.

Commenters offered a variety of alternatives to this proposal including the following:

- Removal of this proposal altogether.
- Allowing ACOs to add TINs on an monthly, quarterly, or annual basis as long as they notify CMS of the modifications to their structure.
- One commenter recommended a ''slot'' approach in rural areas whereby if a TIN leaves the system the ''slot'' may be filled with another TIN.
- Allowing changes in ACO participants of up to 10 percent annually with additional changes in excess of 10 percent to be negotiated as an amendment to the ACO participation agreement.

Response: Although it is imperative that we ensure that ACOs do not make changes to their approved structure that would affect their eligibility to participate in the program, we agree with those comments suggesting that there must be some mechanism to add ACO participants during an agreement period. Accordingly, we will finalize a policy that affords ACOs greater flexibility to deviate from the structure approved in their application. Specifically, we will modify this proposal such that ACO participants and ACO providers/suppliers may be added and subtracted over the course of the agreement period. ACOs must notify us of any additions/subtractions within 30 days. Additionally, ACOs must notify us within 30 days of any significant changes, defined as an event that occurs resulting in an ACO being unable to meet the eligibility or program requirements of the Shared Savings Program. Such a change may cause the ACO to no longer meet the eligibility criteria, for example, losing a large primary care practice could cause the ACOs assigned patient population to fall below 5,000. Furthermore, such changes may necessitate adjustments to the ACO's benchmark, or cause changes to risk scores and preliminary prospective assignment as described in sections II.G and II.E. of this final rule respectively, of this final rule.

Comment: Some commenters also stated that our definitions of significant change and material change were circular.

Response: In this final rule, we have removed the reference to ''material change'' and its accompanying definition. In response to general comments regarding the need to strengthen program requirements, we are finalizing our proposal to require ACOs to notify us within 30 days of any

''significant change,'' which is defined as an event that could cause an ACO to be unable to meet the eligibility or program requirements of the Shared Savings Program. For example, a significant change that affects compliance with eligibility requirements would include losing a large primary care practice that causes the ACO's assigned patient population to fall below 5,000.

Final Decision: Under § 425.214, we are modifying our proposal so that ACO participants and ACO providers/suppliers may be added and subtracted over the course of the agreement period. ACOs must notify us of the change within 30 days of these additions/subtractions of ACO participants or providers/suppliers. Additionally, in the event of ''significant changes'', which is defined as an event that occurs resulting in an ACO being unable to meet the eligibility or program requirements of the Shared Savings Program, the ACO must also notify us within 30 days. Such changes may necessitate, for example, adjustments to the ACO's benchmark, but allow the ACO to continue participating in the Shared Savings Program. Such changes may also cause the ACO to no longer meet eligibility, for example, losing a large primary care practice could cause the ACO assignment to fall below 5,000, and result in termination of the agreement.

5. Coordination With Other Agencies

As mentioned previously, in developing our proposals for the Shared Savings Program, and in response to stakeholder concerns, we worked closely with agencies across the Federal Government to facilitate participation in the Shared Savings Program and to ensure a coordinated and aligned inter- and intra-agency effort in connection with the program. The result of this effort was the release of three documents, concurrently with the Notice of Proposed Rulemaking, including: (1) A joint CMS and DHHS Office of Inspector General (OIG) Notice with Comment Period on Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center addressing proposed waivers of the civil monetary penalties (CMP) law, Federal anti-kickback statute, and the physician self-referral law; (2) an Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Shared Savings Program; (3) a proposed Statement of Antitrust Enforcement Policy Regarding Organizations Participating in the Medicare Shared Savings Program issued by the FTC and DOJ (collectively, the Antitrust Agencies). The comment periods for all of these documents have now closed. Some comments received on this proposed rule were in response to these concurrently released documents, and thus outside the scope of this final rule. We have shared relevant comments with the appropriate agencies.

We have continued working with these agencies while drafting this final rule. As a result a joint CMS and OIG interim final rule with comment period will also be published in the **Federal Register** concurrently with this final rule. The Antitrust Agencies also will publish in the **Federal Register** a final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.

a. Waivers of CMP, Anti-Kickback, and Physician Self-Referral Laws

Certain arrangements between and among ACOs, ACO participants, other owners, ACO providers/suppliers, and third parties may implicate the CMP law (section 1128A(b)(1) and (2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), and/or the physician self-referral prohibition (section 1877 of the Act). Section 1899(f) of the Act authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Program. Accordingly, pursuant to section 1899(f) of the Act, CMS and OIG are jointly publishing an interim final rule with comment period describing waivers applicable to ACOs, ACO participants, and ACO providers/suppliers in the Shared Savings Program. The interim final rule with comment period can be found elsewhere in this issue of the **Federal Register**. The waivers described in the interim final rule with comment period will also apply to the Innovation Center's Advance Payment Model demonstration because ACOs participating in that model will also be participating in the Shared Savings Program.

Comments received in response to the April 2011 proposed rule directed toward the joint CMS and DHHS OIG solicitation will be responded to in the interim final rule with comment period. We encourage reader review of the interim final rule.

b. IRS Guidance Relating to Tax-Exempt Organizations Participating in ACOs

Nonprofit hospitals and other health care organizations recognized by the IRS as tax-exempt organizations are likely to participate in the development and operation of ACOs in the Shared Savings Program. Accordingly, the IRS issued Notice 2011–20 soliciting public comment on whether existing guidance relating to the Internal Revenue Code provisions governing tax exempt organizations is sufficient for those tax-exempt organizations planning to participate in the Shared Savings Program through ACOs and, if not, what additional guidance is needed. For additional information, tax-exempt organizations and ACOs should refer to Notice 2011–20 and other applicable IRS guidance available on *www.irs.gov.*

We also received comments relating to the tax treatment of ACOs. Tax issues are within the jurisdiction of IRS, not CMS. Accordingly, those issues are not addressed in this Final Rule but we have shared the relevant comments with IRS.

c. Antitrust Policy Statement

Concurrently with the issuance of the Shared Savings Program proposed rule, the Antitrust Agencies issued a proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (proposed Antitrust Policy Statement). The proposed Antitrust Policy Statement had several features relevant to the Shared Savings Program, including—

- An antitrust ''safety zone.'' The Antitrust Agencies, absent extraordinary circumstances, would not challenge as anticompetitive ACOs that were within the safety zone. The safety zone also included a rural exception for ACOs operating in rural areas.
- For ACOs outside the safety zone, guidance on the types of conduct to avoid that could present competitive concerns.
- A mandatory Antitrust Agency review procedure for ACOs that met certain thresholds. The mandatory review would be triggered if two or more ACO participants that provide a common service (as defined in the proposed Antitrust Policy Statement) to patients from the same Primary Service Area (''PSA'') have a combined share of greater than 50 percent for that service in each ACO participant's PSA.

The proposed Antitrust Policy Statement described the methodology that ACO participants could use to determine whether the ACO was required to obtain an Antitrust Agency review. Some of the data to be used in this methodology are available at *http://www.cms.gov/sharesavingsprogram/*

35_Calculations.asp. The proposed Antitrust Policy Statement applied to collaborations among otherwise independent providers and provider groups, formed after March 23, 2010 (the date on which the Affordable Care Act was enacted) and that have otherwise been approved to participate, or seek to participate, as ACOs in the Shared Savings Program.

The Antitrust Agencies solicited and received comments on the proposed Antitrust Policy Statement. The Antitrust Agencies are releasing concurrently with this final rule a final Antitrust Policy Statement in response to the comments. Nothing in this final rule shall be construed to modify, impair, or supersede the applicability of any of the Federal antitrust laws. For further guidance on antitrust enforcement policy with respect to ACOs, ACOs should review the final Antitrust Policy Statement.

Comment: Numerous commenters appreciated our work with the Antitrust Agencies to facilitate participation in the Shared Savings Program. However, several commenters suggested we provide additional flexibility to potential ACO applicants and modify the scope of the mandatory antitrust review.

Response: The next section of this final rule discusses our proposals, and addresses all comments, relating to the proposed mandatory antitrust review.

d. Coordinating the Shared Savings Program Application With the Antitrust Agencies

We proposed to require that certain ACOs be subject to mandatory review by the Antitrust Agencies before we would approve their participation in the Shared Savings Program. Specifically, we proposed this mandatory review requirement would apply to any newly formed ACO with a PSA share above 50 percent for any common service that two or more ACO participants provide to patients from the same PSA, and that did not qualify for the rural exception articulated in the proposed Antitrust Policy Statement. Those ACOs would be required to submit to us, as part of their Shared Savings Program applications, a letter from the reviewing Antitrust Agency confirming that it had no present intent to challenge or recommend challenging the proposed ACO. Absent such a letter, the proposed ACO would not be eligible to participate in the Shared Savings Program.

In addition, the proposed Antitrust Policy Statement explained that ACOs that are outside the safety zone and below the 50 percent mandatory review threshold frequently may be pro-competitive. The proposed Antitrust Policy Statement identified five types of conduct that an ACO could avoid to reduce significantly the likelihood of an antitrust investigation. An ACO in this category that desired further certainty regarding the application of the antitrust laws to its formation and planned operation also could seek an expedited review from the Antitrust Agencies, similar to the mandatory review described previously, and similarly would not be eligible to participate in the Shared Savings Program if the reviewing Antitrust Agency reviews the ACO and determines that it is likely to challenge or recommend challenging the ACO as anticompetitive. Finally, we proposed that an ACO that falls within the safety zone would not be required to obtain an Antitrust Agency review as a condition of participation.

Additionally, we recognized in the proposed rule there may be instances during the agreement period where there is a material change (as discussed in section II.C.4. of this final rule) in the composition of an ACO. We proposed that when a material change occurred, the ACO must notify us of the change within 30 days and that the ACO must recalculate and report at that time its PSA shares for common services that two or more independent ACO participants provide to patients from the same PSA. We proposed that if any revised PSA share is calculated to be greater than 50 percent, the ACO would be subject to mandatory review or re-review by the Antitrust Agencies. If the ACO failed to obtain a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO, we proposed that the ACO would be terminated from the Shared Savings Program.

We explained in the proposed rule that the purpose of requiring Antitrust Agency confirmation that it had no present intent to challenge or recommend challenging the ACO as a condition of participation is two-fold. First, it would ensure that ACOs participating in the Shared Savings Program would not present competitive problems that could subject them to antitrust challenge that may prevent them from completing the term of their agreement with us. Second, it would maintain competition for the benefit of Medicare beneficiaries by reducing the potential for the creation of ACOs with market power. In this context market power refers to the ability of an ACO to reduce the quality of care furnished to Medicare beneficiaries and/or to raise prices or reduce the quality for commercial health plans and enrollees, thereby potentially increasing providers' incentives to provide care for private enrollees of higher-paying health plans rather than for Medicare beneficiaries. We stated that competition in the marketplace benefits Medicare and the Shared Savings Program because it promotes quality of care for Medicare beneficiaries and protects beneficiary access to care. Furthermore, competition benefits the Shared Savings Program by allowing the opportunity for the formation of two or more ACOs in an area. Competition among ACOs can accelerate advancements in quality and efficiency. All of these benefits to Medicare patients would be reduced or eliminated if we were to allow ACOs to participate in the Shared Savings Program when their formation and participation would create market power.

Comment: A significant number of commenters opposed mandatory review of ACOs, because an ACO is a new business model designed to encourage collaboration and coordination of care while still providing beneficiaries the freedom of choice of providers under FFS Medicare. The commenters made the following points:

- The Social Security Act, as amended by the Affordable Care Act, does not authorize us either to issue regulations governing the application of the antitrust laws or to delegate to the Antitrust Agencies the authority to block participation in the Shared Savings Program by certain ACOs. These commenters cited a recent article suggesting that the proposed mandatory review confers unreviewable authority on the Antitrust Agencies to disqualify entities from participating in the Shared Savings Program and therefore violates the subdelegation doctrine.[1]
- It is bad public policy to change the nature of antitrust enforcement from law enforcement to a regulatory regime by requiring a mandatory review for ACO applicants with PSA shares greater than 50 percent for common services.
- The mandatory review should be modified such that an ACO's actions, not its size, should be monitored, because if an ACO produces savings while maintaining quality and patient centeredness, market share is not an appropriate measure of anticompetitive behavior.
- Require mandatory notice of the PSA shares, but do not require those ACOs with greater than a 50 percent PSA share to obtain a mandatory review.

[1] Richard D. Raskin, Ben J. Keith, & Brenna E. Jenny, ''Delegation Dilemma: Can HHS Required Medicare ACOs to Undergo Pre-Clearance by the Antitrust Agencies?,'' 20 Health L. Rep. 961 (2011).

• The mandatory review imposes substantial costs on every ACO applicant by requiring them to build their PSA calculations, with a larger burden falling on smaller physician or other physician groups that may not have the tools to do so, thus discouraging their participation. Commenters suggested that we calculate each ACO's PSA shares.

• The proposed antitrust review and CMS application review should occur simultaneously given the tight timeframes to get the program up and running.

• The proposed rule and the proposed Antitrust Policy Statement are inconsistent because the proposed rule does not carve out entities formed before March 23, 2010 from the mandatory review (meaning all entities need a review), whereas the proposed Antitrust Policy Statement does not apply to entities formed before that date.

By contrast, numerous commenters supported the mandatory review to ensure the Shared Savings Program does not become a vehicle for ACOs to obtain market power. Several commenters explained that the consolidation of ACO providers/suppliers into ACOs could have a significant impact on the commercial market. One commenter noted it was important for us to consider ''the impact of competition (or the lack thereof) on quality of care and access to care.'' Several commenters suggested that we lower the threshold for mandatory antitrust review to 40 percent to ensure that there are sufficient providers to allow the formation of competing ACOs to serve Medicare beneficiaries. Another commenter suggested that we carefully consider favoring ACO applications from provider groups without market power while we calibrate and refine the Shared Savings Program.

Response: Based on the comments received, we have reconsidered our approach to coordinating with the Antitrust Agencies. We believe that we can achieve the same two objectives identified in the proposed rule using a less burdensome approach that is consistent with antitrust law enforcement norms and does not raise subdelegation concerns.

Accordingly, in this final rule we are adopting an approach that relies on three prongs to maintain competition among ACOs. First, the Antitrust Agencies will offer a voluntary expedited antitrust review to any newly formed ACO (as defined in the final Antitrust Policy Statement) before it is approved to participate in the Shared Savings Program. We strongly encourage newly formed ACOs that may present competitive issues or are uncertain about their legality under the antitrust laws to take advantage of this opportunity to obtain expedited antitrust review before participating in the Shared Savings Program. This voluntary review will enable ACOs to assess whether they are likely to present competitive concerns that could subject them to an antitrust challenge and prevent them from completing the term of their agreement with us. As noted in the final rule, CMS may terminate an ACO's participation in the Shared Savings Program for, among other reasons, violation of the antitrust laws.

Second, we will provide the Antitrust Agencies with aggregate claims data regarding allowable charges and fee-for-service payments, which will assist the Antitrust Agencies in calculating PSA shares for ACOs participating in the Shared Savings Program. We will share these data with the Antitrust Agencies as soon as the data become available. In addition, we will require ACOs formed after March 23, 2010, to agree, as part of their application to participate in the Shared Savings Program, to permit us to share a copy of their application with the Antitrust Agencies. Both the aggregate data and the information contained in these applications will help the Antitrust Agencies to assess and monitor ACOs' effects on competition and take enforcement action, if appropriate. Third, the Antitrust Agencies will rely on their existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct and filing antitrust complaints when appropriate.

Thus, we are not finalizing our proposal to require mandatory antitrust review and the submission of a letter from a reviewing Antitrust Agency confirming that it has no present intent to challenge, or recommend challenging, an ACO formed after March 23, 2010, that does not qualify for the rural exception articulated in the final Antitrust Policy Statement, and that has a PSA share above 50 percent for any common service that two or more ACO participants provide to patients from the same PSA. In other words, we will not condition Shared Savings Program eligibility on whether an ACO has obtained the requisite letter from the Antitrust Agencies. Rather, we will accept such an ACO into the Shared Savings Program regardless of whether it voluntarily obtains a letter from the Antitrust Agencies and regardless of the contents of any letter it may have voluntarily obtained from the Antitrust Agencies, assuming that the ACO meets the other eligibility requirements set forth in this final rule. We emphasize that the acceptance of an ACO into the Shared Savings Program represents no judgment by CMS about the ACO's compliance with the antitrust laws or the ACO's competitive impact in a commercial market. Moreover, we do not believe that allowing anticompetitive ACOs to operate in commercial markets is necessary for the Shared Savings Program to function effectively.

Again, as noted previously, we encourage newly formed ACOs that desire greater antitrust guidance to seek a voluntary expedited review from the Antitrust Agencies before applying to the Shared Savings Program. All participants in the Shared Savings Program will remain subject to the antitrust laws. In addition, as discussed previously, we released in June 2011 some of the information necessary for ACO applicants to identify common services and to help calculate the relevant PSA shares. The final Antirust Policy Statement describes the procedures for obtaining the voluntary expedited antitrust review.

Although we are eliminating the proposed mandatory review requirement, we still intend to coordinate closely with the Antitrust Agencies throughout the application process and the operation of the Shared Savings Program to ensure that the implementation of the program does not have a detrimental impact upon competition. As discussed in the proposed rule, competition among ACOs participating in the Shared Savings Program will foster improvements in quality, innovation, and choice for Medicare FFS beneficiaries. Section 1899(a)(1)(A) of the Act, which states that ''groups of providers and suppliers meeting criteria specified by the Secretary may work together * * * through an accountable care organization,'' authorizes us to specify eligibility criteria for the ACOs that participate in the Shared Savings Program. As discussed previously, we are using that authority to specify that to be eligible to participate in the Shared Savings Program, an ACO newly formed after March 23, 2010 (as defined in the final Antitrust Policy Statement), must agree to permit us to share its Shared Savings Program application with the Antitrust Agencies. We believe this action is necessary to ensure appropriate monitoring of the competitive effects of ACOs that participate in the Shared Savings Program.

Comment: Several comments recommended we monitor an ACO's per capita health care cost, for both Medicare beneficiaries and commercial

patients. For example, several comments explained that the consolidation of providers to form ACOs could have a significant impact on the commercial market. These commenters explained that through the aggregation of market power, ACOs could have an enhanced incentive and ability to obtain shared savings payments by reducing Medicare expenditures to achieve ''savings'' under the Shared Savings Program, while compensating for the reduced Medicare payments by charging higher rates and possibly reducing quality of care in the private market. This cost shifting could have the effect of raising premiums for enrollees of private and employer-based health plans.

Many of these comments strongly urged us to collaborate with the Antitrust Agencies on data collection and analysis to detect any patterns of anti-competitive practices, including consolidation, that could harm Medicare beneficiaries and enrollees in private markets and threaten the viability of the Shared Savings Program. Other commenters urged us to implement requirements for ACOs to report publicly on the cost and price of care.

Some comments urged us to add requirements to the Shared Savings Program to build a more robust monitoring system for costs. In particular, these comments suggested that we could do the following:

- Require that all participating ACOs have a mechanism for assessing performance on private sector per capita costs by the second year of the program.
- Gather data regarding current market shares, market entries and exits, and pricing trends for the ACOs during the agreement period.
- Set expectations for resource stewardship and waste reduction, including public reporting of quality and cost metrics.
- Specify a standardized set of measures for costs, with input from consumers, purchasers, and other stakeholders.
- Hold ACOs in the Shared Savings Program to a maximum threshold of price increase with their commercial market clients.
- Move to requiring ACOs to take part in all-payer claims databases (APCD) for added transparency.

Response: We agree with commenters that suggested we provide the Antitrust Agencies the data and information to help identify potentially anticompetitive conduct, including consolidation, which could be related to implementation of the Shared Savings Program. Accordingly, we will provide the Antitrust Agencies aggregate claims data regarding allowable charges and fee-for-service payments for ACOs participating in the Shared Savings Program. In addition, we will share copies of applications submitted by ACOs formed after March 23, 2010, with the Antitrust Agencies.

In addition, we have requested that the Antitrust Agencies conduct a study examining how ACOs participating in the Shared Savings Program have affected the quality and price of health care in private markets. We anticipate using the results of this study to evaluate whether we should, in the future, expand our eligibility criteria so that we consider competition concerns more explicitly in the Shared Savings Program application review process.

Comment: Commenters stated that the proposed Antitrust Policy Statement does not mention a process for re-review of the ACO by the Antitrust Agencies for material changes in the ACO's composition. Commenters also stated that the proposed rule's language is circular about the conditions that trigger a ''material'' or ''significant'' change in composition, thus requiring a re-review by the Antitrust Agencies.

Response: As discussed previously, we will no longer require an Antitrust Agency review, such that the commenters' concerns about re-review based on antitrust issues are moot.

Comment: Several commenters suggested that the Shared Savings Program will lead to increased hospital employment of physicians or it will lead to hospital purchases of physician practices, because start-up costs are so great only large entities will be able to afford to participate. As a result, there will be no competition and prices will increase in the commercial sector. Other commenters suggested that hospitals will employ specialist physicians so that they can have patient referrals to related facilities, regardless of price and quality.

Other commenters indicated that hospital employment of physicians will exacerbate the inefficiency problem of physicians being paid a higher rate for performing the same procedures in certain settings. As a result, hospitals will use any market power they have to form hospital-based provider departments and obtain higher rates, through their continued fee-for-service payments, for the same services that could be provided in a less-expensive setting. These comments suggested we adopt policies to safeguard against these practices.

Response: As we discussed in the proposed rule, 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 permits ACO participants that form an ACO to use a variety of collaborative organizational structures, including collaborations short of merger. Indeed, we are also finalizing our proposal that entities that on their own are not eligible to form an ACO can participate in the Shared Savings Program by forming joint ventures with eligible entities. We reject the proposition that an entity under single control, that is an entity formed through a merger, would be more likely to achieve the three-part aim. Moreover, the increased flexibility regarding governing body composition and the leadership and management of an ACO that we are adopting in this final rule demonstrates our belief that different types of entities can be successful in this program.

Comment: Multiple comments discussed the competitive aspects of ACO membership. For example, one commenter suggested that if an urban ACO wants to partner with providers in rural communities, it should be required to allow all providers in the rural community to participate in the ACO if they so choose. Other commenters suggested that an ACO should not be able to use its market power to require smaller providers or suppliers to participate in the ACO (or to prohibit them from participating in the Shared Savings Program as part of a competing ACO) and that we should coordinate with the FTC and DOJ to thwart anti-competitive behavior in the formation of ACOs.

Some commenters requested that we monitor whether ACOs are using information technology requirements to prevent various allied health professionals from participating in an ACO.

Response: We acknowledge the commenters' concerns and remind them that the antitrust laws will continue to apply to the operations and conduct of all ACOs participating in the Shared Savings Program. In other words, if an entity believes that an ACO is engaging in anticompetitive conduct, it can pursue an appropriate private action or bring the conduct to the attention of the Antitrust Agencies.

Final Decision: In sum, we are modifying our proposal. We believe that the voluntary expedited review approach discussed previously, coupled with the Antitrust Agencies' traditional law enforcement authority and our collaborative efforts to share data and information with the Antitrust Agencies, will allow ACOs a reasonable opportunity to obtain guidance

regarding their antitrust risk in an expedited fashion, while also providing appropriate safeguards so that potential or actual anticompetitive harm can be identified and remedied. We are finalizing these policies at § 425.202. However, we will continue to review these policies and adjust them accordingly as we gain more experience with the Shared Savings Program.

D. Provision of Aggregate and Beneficiary Identifiable Data

1. Data Sharing

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.'' Further, 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 * * *.'' 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, and conducting population-based activities relating to improved health. 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. Moreover, this ability to self-manage is a critical skill for each ACO to develop, leading to an understanding of the unique patient population that it serves.

However, as we discussed in the proposed rule, although an ACO typically should have, or is moving towards having complete information for the services it provides to its assigned beneficiaries, we also recognize that the ACO may not have access to complete information about all of the services that are provided to its assigned beneficiaries by providers outside the ACO—information that would be key to its coordinating care for its beneficiary population. Therefore, we proposed to generate aggregate data reports, to provide limited identifying information about beneficiaries whose information serves as the basis for the aggregate reports (and who are preliminarily prospectively assigned), and to share beneficiary identifiable claims data with the ACO unless the beneficiary chooses to decline to share their data. As we stated in the proposed rule, we believe that access to this information would provide ACOs with a more complete picture about the care their assigned beneficiaries receive both within and outside the ACO. It would also enable the ACOs to ascertain their ACO participants and ACO providers'/suppliers' patterns of care, and could be used to assess their performance relative to their prior years' performance.

As noted in the proposed rule, the disclosure of this information in accordance with applicable privacy and security requirements would enable an ACO to be better able to identify how its ACO participants and ACO providers/suppliers measure up to benchmarks and targets, how they perform in relation to peers internally, and to identify and develop a plan for addressing the specific health needs of its assigned beneficiary population.

2. Sharing Aggregate Data

In the proposed rule, we discussed supplementing the information ACOs will be gathering as part of their internal processes for monitoring and improving care furnished to its assigned beneficiary population with aggregated (de-identified) data on beneficiary use of health care services.

We proposed to provide aggregate data reports at the start of the agreement period that would be based on data for those beneficiaries historically assigned (hereafter referred to as preliminary prospectively assigned beneficiaries), and included in the calculation of the ACO's benchmark. These reports would include, when available, aggregated metrics on the beneficiary population and beneficiary utilization data at the start of the agreement period, based on the historical data used to calculate the benchmark. We further proposed to include these data in conjunction with the yearly financial and quality performance reports. Additionally, we proposed to provide quarterly aggregate data reports to ACOs based upon the most recent 12 months of data from potentially assigned beneficiaries. We requested comments on these proposals. For a comprehensive review of our proposals and rationale, see section II.C.4. of the proposed rule (76 FR 19555).

Comment: The comments received were supportive of the proposal to provide aggregate data to ACOs but suggested that this data would not be useful unless it was delivered in a timely manner. Recommendations included providing the aggregate data set prior to the submission of an application, quarterly, immediately following the reporting period, or in real time. A few commenters expressed concerns that aggregate reports based upon a historical population may not provide the ACO with sufficient information to make appropriate changes for its future fee-for-service population.

Response: Although we intend to provide these aggregate data reports in a timely manner, it will not be possible to provide these reports to ACOs in ''real time.'' The aggregate reports would be derived from provider and supplier claims data. Claims data are only available after they have been submitted and processed. As such, there is an inherent delay between when a service is performed and when a claim is processed. This process delay is in addition to the time it takes to prepare this claims level data to an aggregate level data set. Both of these factors make it impossible to provide aggregate data reports to ACOs in ''real time.''

It is also not possible to provide aggregate data reports prior to the submission and approval of an ACO application and the ACO signing its participation agreement. The aggregate data report is based upon the ACO application itself and the TINs and NPIs that enter into an agreement with the ACO. Until we have received and reviewed the applications, determined the eligibility of the ACO participants and ACO providers/suppliers to participate, and received a signed DUA from the ACO, we cannot begin to construct the aggregate data reports. Finally, in response to those who expressed concern about the utility of historic data, we note that we proposed to supply the aggregate data report historically for the benchmark, quarterly and in conjunction with the yearly financial and quality performance reports, the provision of this data in subsequent years of the agreement period is already a component of our proposed policy.

Additionally, our experience with the PGP demonstration and modeling of our proposed methodology for identifying beneficiaries associated with the ACO suggests that a high percentage of patients who chose ACO participants and ACO providers/suppliers in the benchmark period will continue to receive care from these ACO participants and ACO providers/suppliers. We believe knowing

individuals who would have been assigned in the past will help the ACO participants identify the kinds of interventions that are likely to improve care for their fee-for-service population going forward.

Comment: Several commenters were concerned about the delivery, format, and content of the aggregate data report. Several commenters questioned the ability of CMS to deliver accurate, relevant, and comprehensive data to ACOs and suggested that CMS outline a detailed plan to improve its data delivery system. Commenters felt that the data should be standardized by CMS as aggregate data would be too complex for many organizations to analyze. Commenters also suggested that the aggregate data reports must include: Links to the beneficiary identifiable data and health quality indicators, comparative regional and national claims data, and separate aggregate data on patients that have chosen to ''opt-out of the shared savings program.'' A few comments suggested that we provide customized reports to each ACO. Finally, one commenter suggested that CMS should also supply aggregate savings/losses reports to ACOs quarterly.

Response: We proposed to deliver aggregate data reports to ACOs at the start of the agreement period, quarterly, and in conjunction with the annual quality and financial reports. These data extractions would be standardized reports for all ACOs. It would not be administratively feasible to offer customized reports for each ACO. We expect that ACOs would be able to incorporate the aggregated data reports into their own data processing systems for use in developing population health management capabilities. By its nature, aggregate data cannot be linked to individual beneficiary identifiable data as the purpose of the aggregate data is to offer a broad view of the overall population of assigned beneficiaries and potential areas for improvement. Additionally, the aggregate data will not be linked to specific quality indicators as this is not the purpose of providing the standardized aggregate data reports. The ability to receive lists of beneficiaries whose data were used to compile the aggregate data reports and monthly beneficiary identifiable claims data, as discussed later in this final rule, in conjunction with the aggregate data reports, will afford ACOs the opportunity to use the lessons learned from the aggregate data reports to implement delivery system reforms appropriate for their own beneficiary populations. While we did not propose to offer regional or national aggregate data reports or include a report on beneficiaries that have declined to share their protected health information (PHI), we think these suggestions merit consideration and we will keep them in mind during future rulemaking cycles. For now, aggregate data reports will be provided on the assigned beneficiary population, including beneficiaries who may have declined to share their PHI data.

Finally, due to the inherent delay in receiving and processing claims level data, it would not be feasible or accurate to supply shared savings/loss reports to ACOs quarterly. However, the quarterly reports will include information on per capita expenditures for assigned beneficiaries that ACOs can use to monitor and improve their performance.

Final Decision: We will finalize without change our proposals related to sharing of aggregate data (see part 425 subpart H in regulatory text of this final rule).

3. Identification of Historically Assigned Beneficiaries

Based on feedback from the PGP demonstration, the RFI comments on the Shared Savings Program, and the Shared Savings Program Open Door Forums, we proposed to make certain limited beneficiary identifiable information available to ACOs at the beginning of the first performance year. We believed ACOs would benefit from understanding which of their FFS beneficiaries were used to generate the aggregated data reports. Accordingly, we proposed to disclose the name, date of birth (DOB), sex and Health Insurance Claim Number (HICN) of the preliminary prospective assigned beneficiary population. We believed that knowing these data elements would be useful to the ACO in two ways: First, the ACO participants and ACO providers/suppliers could use the information to identify the preliminary prospective assigned beneficiaries, review their records, and identify care processes that may need to change. Second, experience with the PGP demonstration has suggested that a high percentage of preliminary prospective assigned beneficiaries will continue to receive care from the ACO participants and ACO providers/suppliers.

We recognized that there are a number of issues and sensitivities surrounding the disclosure of individually-identifiable (patient-specific) health information, and noted that a number of laws place constraints on the sharing of individually identifiable health information. We analyzed these issues and legal constraints and concluded that the proposed disclosure of the four identifiers would be permitted under the applicable laws and address the issues raised, subject to the conditions described in detail in the proposed rule (76 FR 19555), and we sought comment on this proposal.

Comment: Although the majority of comments supported our proposal to supply ACOs with the name, DOB, sex and HICN of the preliminary prospective assigned beneficiary population, we did receive a few comments that objected to this proposal. Of those comments that disagreed with our proposal, the concerns were related to the confusion that could result for ACO participants and ACO providers/suppliers related to the provision of data on the preliminary prospective assigned beneficiaries who may not choose to see ACO participants or ACO providers/suppliers going forward, the potential for ACOs to use the proposed data elements to avoid at-risk and/or high cost beneficiaries, and the legality of disclosing this type of data. Others suggested the four data points be expanded to include other beneficiary identifiable information.

Response: We proposed providing limited beneficiary identifiable information to ACOs at the start of the agreement period in order to assist the ACO in conducting population-based activities related to improving health or reducing costs, protocol development, case management and care coordination. We believed that the ACO could use the information to identify the preliminary prospective assigned beneficiaries, review their records, and identify care processes within its organization that may need to change. Since a high percentage of beneficiaries who choose ACO participants and ACO providers/suppliers in the benchmark period will continue to receive care from these ACO participants and ACO providers/suppliers, we do not believe this data set will generate any confusion for ACOs. As we outlined in the proposed rule, we believe the agency has legal authority to provide this data to ACOs. As also discussed in the proposed rule, we believe these particular data elements will be useful to the ACO for two reasons: (1) The ACO participants and ACO providers/suppliers could use the information to identify the preliminary prospectively assigned beneficiaries, review their records, and identify care processes that may need to change, and (2) experience with the PGP demonstration has suggested that a high percentage of preliminary prospective assigned beneficiaries will continue to receive care from the ACO participants and ACO providers/suppliers. We

believe that the proposed four data points will be sufficient to aid ACOs in focusing their initial care redesign efforts going forward. We also believe these four data points are the minimum data necessary for providers to begin the process of developing care plans in an effort to provide better care for individuals and better health for populations. As described in section II.D.4 of this final rule, the ACO would have the additional opportunity to request claims data for these individuals after having given these beneficiaries the opportunity to decline such data sharing. Finally, we agree with the comment that while providing such information may be a benefit to both the beneficiary and the ACO, concerns remain that ACOs could use it to avoid at-risk beneficiaries or to stint on care. For this reason we have included in section II.H. of this final rule a detailed discussion of the safeguards and sanctions that have been incorporated into the program to guard against avoidance of at-risk beneficiaries.

Comment: Several comments suggested that we provide the limited beneficiary identifiable data set in advance of ACOs signing agreements.

Response: The limited beneficiary identifiable data set is constructed based upon the content of the ACO's application, including the associated TINs that have been verified as part of the application process. The data would be comprised of information regarding the beneficiaries who would have met the criteria for assignment to the ACO during the benchmark period. Without a verified list of eligible TINs that will be associated with the ACO, we cannot construct this data set. Additionally, as discussed later in this final rule, we will require ACOs to enter into a Data Use Agreement (DUA) prior to receipt of any beneficiary identifiable claims data, and this agreement can only be executed after an applicant has been approved to participate in the Shared Savings Program as an ACO.

Under HIPAA and the required business associate agreements, the ACO and its participants will not be able to use or disclose any individually identifiable health information it receives from us in a manner in which a HIPAA covered entity would be barred from doing. Furthermore, under the DUA, the ACO would be prohibited from sharing the Medicare claims data that we provide through the Shared Savings Program with anyone outside the ACO that has not co-signed the DUA as a contractor to the ACO. In addition, ACOs must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the ACO program's statutory and regulatory requirements. Compliance with the DUA will be a condition of the ACO's participation in the Shared Savings Program—non-compliance with this requirement would result in the ACO no longer being eligible to receive data, and could lead to termination from the Shared Savings Program or additional sanctions and penalties available under the law.

For these reasons, we cannot disclose beneficiary identifiable information to an ACO until such time as any necessary Business Associate Agreements (BAAs) between an ACO and its ACO participants and ACO providers/suppliers are established in accordance with HIPAA and there is a signed DUA in place with us.

Comment: Several comments requested that at the start of the agreement period, we provide more detailed and robust beneficiary identifiable data than the four data points identified and that we update and provide to ACOs the list of the potentially assigned beneficiary population monthly or quarterly.

Response: Although we understand that ACOs would prefer to have more detailed beneficiary identifiable data at the start of the agreement period, in the proposed rule (76 FR 19555) we described the minimum necessary data elements we believed were essential to accomplish the health care operations described in the NPRM. As discussed in response to a previous comment, we believe that the proposed four data points will be sufficient to aid ACOs in focusing their care redesign efforts initially. As noted in section II.D.4. of this final rule, however, the ACO will have the opportunity to request additional claims data for these beneficiaries once the ACO has given them the opportunity to decline data sharing.

As described in section II.E. of this final rule, we are modifying our proposed assignment methodology to provide ACOs preliminary prospective assignment of beneficiaries with retrospective reconciliation based on actual beneficiary utilization. We agree with commenters that providing quarterly aggregate reports on the preliminarily prospective assigned population would assist ACOs in conducting population-based activities relating to improving health or reducing costs, protocol development, case management and care coordination. Therefore, we will be providing ACOs with quarterly listings of preliminarily prospective assigned beneficiary names, DOB, sex, and HCINs that were to generate each quarterly aggregate data report. We believe that the provision of the quarterly aggregate reports and the limited identifiable information on beneficiaries used to generate the reports, combined with the opportunity to request monthly beneficiary identifiable claims data as discussed later in this final rule, and our modification to allow ACOs to request claims data of beneficiaries that appear on these reports, will provide sufficient information for treatment and health care operations activities with the Medicare FFS population for which it is accountable.

Final Decision: We are finalizing our proposal to provide the ACO with a list of beneficiary names, dates of birth, sex, and HICN derived from the beneficiaries whose data was used to generate the preliminary prospective aggregate reports (Subsection H). We are modifying our proposal to provide similar information in conjunction with each quarterly aggregated data report, based upon the most recent 12 months of data, consistent with the time frame listed in the proposed rule.

4. Sharing Beneficiary Identifiable Claims Data

While the availability of aggregate beneficiary information and the identification of the beneficiaries used to determine the benchmark will assist ACOs in the overall redesign of care processes and coordination of care for their assigned beneficiary populations, we believe that more complete beneficiary-identifiable information would enable practitioners in an ACO to better coordinate and target care strategies towards the individual beneficiaries who may ultimately be assigned to them. There are recognized limits to our data, however, and to our ability to disclose it.

After consideration of the legal limitations and policy considerations that would be applicable to disclosure of these data, which are discussed in detail in the proposed rule (76 FR 19557 through 19559), we proposed to give the ACO the opportunity to request certain beneficiary identifiable claims data on a monthly basis, in compliance with applicable laws. We proposed to limit the available claims to those of beneficiaries who received a primary care service from a primary care physician participating in the ACO during the performance year, and who have been given the opportunity to decline to have their claims data shared with the ACO but have declined to do so. Furthermore, we proposed that beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug

abuse patient records (42 CFR Part 2) would only be made available if the beneficiary provided his or her prior written consent. Finally, we proposed to limit the content of the claims data to the minimum data necessary for the ACO to effectively coordinate care of its patient population.

As a condition of receiving the data, the ACO would be required to submit a formal data request, either at the time of application or later in the agreement period, and explain how it intends to use these data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population.

Additionally, we proposed to require ACOs to enter into a DUA prior to receipt of any beneficiary-identifiable claims data. Under the DUA, the ACO would be prohibited from sharing the Medicare claims data that we provide through the Shared Savings Program with anyone outside the ACO. In addition, we proposed to require in the DUA that the ACO agree not to use or disclose the claims data, obtained under the DUA, in a manner in which a HIPAA covered entity could not without violating the HIPAA Privacy Rule. We proposed to make compliance with the DUA a condition of the ACO's participation in the Shared Savings Program—non-compliance with this requirement would result in the ACO no longer being eligible to receive data, and could lead to its termination from the Shared Savings Program or additional sanctions and penalties available under the law. ACOs would be required to certify to their willingness to comply with the terms of the DUA in their application to participate in the program or at the time they request the claims data, we solicited comments on our analysis and proposals described previously. For a complete discussion of our analysis of our legal authority to disclose beneficiary-identifiable parts A, B, and D claims data to ACOs (see 76 FR 19556 through 19559).

Comment: The majority of comments supported the provision regarding beneficiary-identifiable data. However, some expressed concern about the ability of CMS to provide timely data to ACOs. The majority of comments supported the provision of this data on a monthly basis but some comments requested a more streamlined approach that would enable the provision of this data ''real time'' or weekly.

One commenter believed that claim-based data simply cannot be timely, stating that by the time a claim for a service is submitted, processed and adjudicated, and compiled and extracted, significant time will have elapsed. Additionally, the commenter also contended that by the time the monthly transfer is received and properly ''loaded'' on an ACO's system, and analyzed by the ACO's or their consultant's staff, several more months will have elapsed, rendering the data less than useful. Another commenter suggested these data would be useful on a quarterly basis.

Response: Although we understand that ACOs would like to obtain data on a real time, or nearly real time basis, as we explained in the proposed rule, there is an inherent lag between when a service is performed and when the service is submitted for payment, for this reason it is not feasible to provide data in real time. As noted previously, however, 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. A robust health information exchange infrastructure and improving communication among ACO participants and the ACO's neighboring health care providers could assist in accessing data that is closer to ''real time''.

In keeping with the ''minimum necessary'' provisions of the HIPAA Privacy Rule, ACOs are expected only to request data from us that will be useful to them for conducting the kinds of activities that are described in the proposed rule. ACOs may request data as frequently as each month but are not required to submit a request monthly. ACOs may submit requests less frequently if monthly reports are not necessary to suit their needs.

Comment: Several comments were concerned about the ability of ACOs to convert a large volume of claims data into actionable information. Some requested that CMS standardize the monthly information in a way that is actionable for the ACO.

Response: We agree that not all ACOs may have the capability, desire, or need to handle large volumes of claims data in a way that will complement the ACO's activities to improve care processes. For that reason, we are not requiring all ACOs to submit DUAs or request monthly beneficiary identifiable claims data, as noted previously. Accordingly, as described previously, before receiving any data, the ACO will be required to explain how it intends to use these data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population.

Comment: A few comments requested that the data elements contained in the monthly beneficiary identifiable data be expanded. Commenters additionally suggested that the data elements should include detailed information on all services received by beneficiaries who have been treated by an ACO participant. One comment specifically requested that the claims data include both the NPI and TIN so they can drill their quality and cost containment efforts down to the individual provider level while another comment specifically requested that for suppliers, such as laboratories, the minimum necessary data set must include the Place of Service (POS) code as the supplier ID serves no real purpose for laboratories.

Response: In the proposed rule, we stated that we believed the minimum necessary Parts A and B data elements would include data elements such as: Procedure code, diagnosis code, beneficiary ID, date of birth, gender, and, if applicable, date of death, claim ID, the form and thru dates of service, the provider or supplier type, and the claim payment type. (76 FR 19558). Similarly, we stated that the minimum necessary Part D data elements could include data elements such as: Beneficiary ID, prescriber ID, drug service date, drug product service ID, and indication if the drug is on the formulary. (76 FR 19559). We would like to clarify that these lists of data elements were provided in order to offer examples of the types of data elements that might be the minimum data necessary to permit an ACO to undertake evaluation of the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities with and on behalf of the ACO participants and ACO providers/suppliers, and conduct population-based activities relating to improved health for Medicare beneficiaries who have a primary care visit with a primary care physician used to assign patients to the ACO during a performance year. We did not, however, intend that these data elements would be the only data elements that an ACO could request. Rather, we intended that an ACO could request additional data elements provided it could demonstrate how the additional requested information would

be necessary to performing the functions and activities of the ACO, such that they would be the minimum necessary data for these purposes. Accordingly, in this final rule, we are clarifying that the minimum necessary data elements may include, but are not limited to, the list of Parts A and B data elements and the list of Part D data elements that were specifically included in the proposed rule.

Furthermore, we agree with the request to include the provider's identity, such as through the NPI or TIN. One of the important functions of the ACO is to coordinate care, and without the provider's identity, the ACO would not able to make full use of the claims data to determine which other providers it will need to work with in order to better coordinate the beneficiary's care. For the same reasons, the POS code will be useful. We do agree that in order to effectively evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population the minimum necessary data set should be expanded to include TIN, NPI, and POS codes.

Comment: Several commenters requested that beneficiary identifiable data be supplied to ACOs 6 months prior to their initial agreement start date while other comments did not specify a specific timeframe but generally requested that beneficiary identifiable data be provided to ACOs in advance of signing their agreements.

Response: Similar to the response provided previously related to the provision of the four beneficiary identifiable data points associated with the aggregate data reports, the legal bases for the disclosure of beneficiary-identifiable information would not be applicable prior to the start of the ACO's participation in the Shared Savings Program.

Comment: Several comments requested that we make Medicare claims data available to Regional Health Improvement Collaboratives as soon as possible so that they can help providers in their community identify successful strategies for forming ACOs and also develop other innovative payment and delivery reforms that the Innovation Center can support.

Response: This comment is outside the scope of this rule. In the proposed rule, we proposed to share beneficiary-identifiable claims data with the ACOs under the terms specified. We did not propose to make these data available to other entities. However, we note that under section 10332 of the Affordable Care Act certain qualified entities, which may include existing community collaboratives, that meet certain requirements for performance measurement and reporting can access beneficiary identifiable claims data for the purposes of evaluating the performance of providers and suppliers on measures of quality, efficiency, effectiveness and resource use.

Comment: One comment recommended that ACOs should be required to assure that health data is bi-directional with State health agency registries. This bi-directional sharing of data is an important resource to draw on the expertise of governmental public health in using data to identify high risk populations. State health agencies can provide improvements in individual and population care, resulting in better health and reduced expenditures.

Response: We recognize the importance of encouraging health information exchange with State health agency registries. Two of the objectives of our Medicare EHR Incentive Program for eligible professionals are related to sharing information with State health agencies, such as immunization data and syndromic surveillance data. More information about the Medicare EHR Incentive Program is available at *https://www.cms.gov/ehrincentiveprograms/30_Meaningful_Use.asp.* As discussed in section II.F. of this final rule, we have adopted a quality measure requiring ACOs to report the percentage of primary care providers who successfully qualify for an EHR Incentive Program payment.

We anticipate that ACOs will participate in active health information exchange with their State health agencies as appropriate; however, we decline to require ACOs to send information to their State health agencies as a condition of participation in the Shared Savings Program. We are finalizing our proposal to share beneficiary identifiable data with ACOs that are qualified to participate in the program.

Comment: Several commenters were concerned that the integrated design of ACOs could result in DUA and privacy law violations without appropriate monitoring and safeguards in place, and would request that CMS be more prescriptive in those policies addressing its sharing of data, the ACOs sharing of data internally, and the ACO's suppression of inappropriate data flowing to sources (that is adolescent/minor data to a parent/guardian, beneficiary data to an ex-spouse, etc.).

Response: As discussed previously, we believe we have the legal authority to share beneficiary identifiable claims data under the conditions specified. While not required to do so under the applicable laws, we have also elected to bar redisclosure of any CMS claims data that are received by an ACO through the Shared Savings Program. Furthermore, the recipients of CMS claims data under this program are either HIPAA covered entities or business associates of HIPAA covered entities. The HIPAA Privacy and Security rules will provide added protections (and enforcement mechanisms) outside of the ACO program requirements. Additionally, we have proposed, and are finalizing robust monitoring protocols (described in section II.H. of this final rule) that will protect beneficiary privacy interests and penalize ACOs that misuse data.

Comment: A comment stated that CMS must assure that all ACO participants have equal access to beneficiary identifiable data. Another commenter recommended that pharmacists specifically be allowed to be active partners in data sharing.

Response: We believe it is in the best interest of all ACO participants to have a voice in the decision making and function of the ACO. As such, we have proposed that ACO participants (defined as any Medicare enrolled provider or supplier, including pharmacists) have a mechanism of shared governance. Shared governance ensures all ACO participants have the ability to jointly make decisions on how best to use and disseminate information derived from beneficiary identifiable claims in accordance with all applicable laws for purposes of the health care operations of the ACO participants, and/or effectively treating the assigned patient population of the ACO.

Comment: Several comments expressed concerns regarding how the data for those patients that are ultimately not assigned to the ACO will be handled. One comment specifically requests that no beneficiary identifiable data be shared with any program until after the Medicare Advantage open season has concluded as this would ensure that a Medicare beneficiary has the option of electing a different health care delivery method without having their personal information shared with an organization through which they are not receiving health services.

Response: We recognize that some beneficiaries will not continue to see the ACO participants because they may move or change providers. Some beneficiaries may change providers because they have enrolled in a Medicare Advantage plan that does not

include their existing provider. When beneficiaries stop receiving care from ACO participants, for whatever reason, the ACO no longer needs to receive claims data for these beneficiaries because the ACO would no longer be responsible for coordinating their care. Accordingly, consistent with § 425.704(b), ACOs should not continue to request claims data from us for beneficiaries that the ACO knows are no longer being treated by ACO participants.

We are finalizing our proposal to share these data with the ACO once the beneficiary has been notified and has not declined to have their data shared. We will also monitor the ACO's compliance with the terms of the DUA.

Comment: Several commenters recommended that we specify in the regulation that an ACO may transmit data to a vendor or designate a vendor to receive data from CMS on their behalf, and that this vendor may use this data in a manner that complies with HIPAA and their business associate agreements.

Response: In the proposed rule, we discussed the ability under HIPAA for covered entities to share beneficiary identifiable data with business associates. We believe based on its work on behalf of covered entity ACO participants and ACO providers/suppliers in conducting quality assessment and improvement activities, a vendor could qualify as a business associate or subcontractor of a business associate. Therefore, we believe an ACO may allow a vendor to receive claims information on its behalf, but it must assume responsibility for that vendor's use and disclosures of the data.

Comment: One comment suggested that the provision of beneficiary identifiable data on a monthly basis could undermine the movement to EHRs if ACOs instead invest in free-standing programs to analyze claims data. Other comments state that the ability to facilitate health information exchange among affiliated and unaffiliated providers through the use of both EHR and HIT interoperability standards is an important ingredient to the success of ACOs.

Response: We disagree that the movement toward adopting EHRs will be somehow undermined by our provision of beneficiary identifiable claims data to the ACOs. As we have explained, the beneficiary identifiable claims data that will be furnished by us, although useful, is not ''real time'' and is not expected to supplant the expectation that ACOs are growing in their capability for internal analysis of data to improve quality as well as improving coordination of care by better communication between ACO participants and non-participant providers. Additionally, because the ACO will be held accountable for an assigned population of FFS Medicare beneficiaries, we expect that beneficiary identifiable claims data will be useful in identifying services and goods obtained from non-ACO providers and suppliers and in developing processes to improve communication with those practitioners to improve overall care delivery. The development of interoperable EHR and HIT among both affiliated and unaffiliated providers would be one way to facilitate communication with practitioners.

5. Giving Beneficiaries the Opportunity To Decline Data Sharing

Although we have the legal authority, within the limits described previously, to share Medicare claims data with ACOs without the consent of beneficiaries, we nevertheless believe that beneficiaries should be notified of, and have control over, who has access to their personal health information for purposes of the Shared Savings Program. Thus, we proposed to require that, as part of its broader activities to notify patients that its ACO provider/supplier is participating in an ACO, the ACO must also inform beneficiaries of its ability to request claims data about them if they do not object.

Specifically, we proposed that when a beneficiary has a visit with their primary care physician, their physician would inform them at this visit that he or she is an ACO participant or an ACO provider/supplier and that the ACO would like to be able to request claims information from us in order to better coordinate the beneficiary's care. If the beneficiary objects to sharing their data, he or she would be given a form stating that they have been informed of their physician's participation in the ACO and explaining how to decline having their personal data shared. The form could include a phone number and/or email address for beneficiaries to call and request that their data not be shared. Thus, we proposed that ACOs would only be allowed to request beneficiary identifiable claims data for beneficiaries who have: (1) Visited a primary care participating provider during the performance year; and (2) have not chosen to decline claims data sharing. We noted that it is possible that a beneficiary would choose not to have their data shared with the ACO but would want to continue to receive care from ACO participants or providers/suppliers. We further noted that in such a case, the ACO would still be responsible for that beneficiary's care, and as such, the beneficiary's data would continue to be used to assess the performance of the ACO. To ensure a beneficiary's preference is honored, we proposed to maintain a running list of all beneficiaries who have declined to share their data. We proposed to monitor whether ACOs request data on beneficiaries who have declined data sharing, and proposed to take appropriate actions against any ACO that has been to make such a request. For a complete discussion of our policy rationale for these proposals (see (76 FR 19559 and 19560)).

Comment: Some comments suggested that this proposal to permit beneficiaries to decline data sharing runs counter to the goal of coordinated care and will make it nearly impossible for ACOs to succeed. These comments offered various alternatives ranging from: Eliminating the opportunity for beneficiaries to decline data sharing, removing those beneficiaries who elect to decline to have their data shared from ACO performance assessment, requiring beneficiaries who choose to decline to participate in data sharing from continuing to seek care from an ACO participant, allowing ACOs to refuse care to beneficiaries who choose to decline data sharing, and making the beneficiary's choice to receive care from an ACO provider/supplier an automatic opt-in for data sharing.

Response: Although we have the legal authority, within the limits described previously, to share Medicare claims data with ACOs without the consent of the Medicare beneficiaries, we believe that beneficiaries should be notified of their provider's participation in an ACO and have some control over who has access to their personal health information for purposes of the shared savings program. Furthermore, we believe that a beneficiary should not be subject to any penalties, such as being required to change their healthcare provider, if they decide that they do not want their information shared. The requirement that an ACO provider/supplier engage patients in a discussion about the inherent benefits, as well as the potential risks, of data sharing provides an opportunity for true patient-centered care and will create incentives for ACOs, ACO participants, and ACO providers/suppliers to develop positive relationships with each beneficiary under their care. Additionally, this proposal will provide ACO participants and ACO providers/suppliers the opportunity to engage with beneficiaries by explaining the shared savings program and its potential benefits to both the beneficiaries and the health

care system as a whole. FFS beneficiaries will retain their right to seek care from any provider, including those participating in an ACO, even if they decline to share their data. Additionally, requiring that ACOs be accountable to all assigned beneficiaries will allow us to compare the quality metrics and costs between those beneficiaries who have declined to share their data and those beneficiaries who have allowed their data to be shared in order to evaluate the effectiveness of the data sharing provisions. We will monitor for any actions taken on the part of the ACO to steer patients away that have declined data sharing.

Comment: A few comments recommend that for the elderly, less literate or tribal populations, that an opt-in approach would be more conducive to offering beneficiaries meaningful control over their personal health information. Commenters believe the advantage of an opt-in approach is that consent must be sought before which time any sharing of health information can occur. Obtaining affirmative written permission would also provide documentation of the beneficiary's choice. A few other comments supported our policy to afford meaningful choice over their personal health information to beneficiaries but recommended that we make this less burdensome on the beneficiary.

Response: We disagree that an opt-in approach would offer beneficiaries more control over their personal health information then an opt-out approach. We believe either approach, done well, offers equivalent control. As discussed previously, our opt-out approach coupled with notification of how protected health information will be shared and used affords beneficiaries choice and will offer ACOs, ACO participants, and ACO providers/suppliers the opportunity to develop positive relationships with each beneficiary under their care. Additionally, our notification and opt out approach will provide ACOs, ACO participants, and ACO providers/suppliers the opportunity to explain the shared savings program and its inherent benefits to both the beneficiaries and the health care system as a whole. We recognize that obtaining affirmative written permission would provide documentation of the beneficiary's choice in an opt-in model. However, we believe that under this approach significant paperwork burdens arise as providers must track consents for the majority of their patient population.

Comment: One comment stated that requiring beneficiaries to change their health care delivery in order to avoid having their personal health information shared among ACO providers is contrary to the message delivered during the health care debate that if a beneficiary was happy with their health care, nothing would change. Another comment was concerned that patients may be skeptical of or not understand the opt-out proposal and for this reason seek care outside the ACO, even if the beneficiary has an established relationship with the ACO participant.

Response: We disagree with this comment and contend that the transparency provided by this proposal ensures the beneficiary may decline data sharing while also allowing the beneficiary to continue to receive care from an ACO provider if they are happy with the care he/she is providing. In this way, beneficiaries retain freedom under traditional FFS Medicare to choose their own health care providers while also affording them the option of whether or not to share their data.

Comment: Several comments approved of our proposal to offer all beneficiaries the opportunity to decline to share their health data and especially liked that it would afford providers the opportunity to engage with patients to promote trust. Many of these comments also suggested that this policy would allow CMS to evaluate whether or not the sharing of beneficiary identifiable claims data is an important factor in improving health care delivery by comparing outcomes for beneficiaries who decline data sharing against those who do not.

Response: We agree that evaluating the outcomes of beneficiaries who have declined data sharing versus those who have not could provide valuable information, and will investigate the possibility of conducting such a study. We believe comparative evaluations like this are important for identifying potential improvements to improving the Medicare program. We intend to study the effects of the Shared Savings Program over time, and expect to improve the program through lessons learned by participants and evaluations of similar initiatives, such as those undertaken through the Innovation Center.

Comment: A few commenters recommended that CMS maintain the list of beneficiaries who have declined to share their data, and that CMS report to the ACOs the percentage of attributed beneficiaries who decline data sharing to the ACO since this will directly impact data integrity, risk assessment, validation, and potentially performance.

Response: We agree that knowing the percentage of beneficiaries that have declined data sharing could be useful to ACOs. However, because the ACO will be compiling and submitting the list of beneficiaries who have not declined data sharing on a monthly basis, the ACO will already have sufficient data to assess the percentage of beneficiaries who decline data sharing.

Comment: A few comments suggest that CMS explore alternative assignment methodologies that will facilitate a greater willingness by beneficiaries to share data. Additionally, one commenter recommended that the data sharing process proposed in the Pioneer ACO Model should be adopted for the general Shared Savings Program.

Response: We appreciate these comments and are looking forward to lessons learned from testing different approaches in the Pioneer ACO Model.

Comment: Several commenters were concerned that allowing ACOs access to beneficiary identifiable data only after: (1) The beneficiary has visited a primary care participating provider during the performance year; and (2) does not elect to decline to participate in data sharing, will result in a delay in the provision of claims data to ACOs, and may generate unnecessary office visits for the beneficiary population as providers might attempt to pull beneficiaries into the office for needless visits just in order to explain the Shared Savings Program to the beneficiaries.

Response: We have considered these comments in light of our goal to promote better physician-patient relationships, program transparency and reduce administrative burden. We are modifying our proposed approach to providing beneficiary identifiable data to ACOs. We will continue to require ACOs to notify patients at the point of care that they are participating in an ACO, that they will be requesting PHI data, and that the beneficiary has the right to decline to share this data with the ACO. In addition, we will also provide a mechanism by which ACOs can notify beneficiaries and request beneficiary identifiable data in advance of the point of care visit using the lists of preliminary prospectively assigned patients provided to the ACO at the start of the agreement period and quarterly during the performance year.

As discussed previously, upon signing participation agreements and a DUA, ACOs will be provided with a list of preliminary prospectively assigned set of beneficiaries that would have historically been assigned and who are likely to be assigned to the ACO in future performance years. ACOs may utilize this initial preliminary

prospectively assigned list along with the quarterly lists to provide beneficiaries with advance notification prior to a primary care service visit of their participation in the shared savings program and their intention to request their beneficiary identifiable data. Beneficiaries will be given the opportunity to decline this data sharing as part of this notification. After a period of 30 days from the date the ACO provides such notification, ACOs will be able to request beneficiary identifiable data from us absent an opt-out request from the beneficiary. Although we would expect providers/suppliers to still actively engage beneficiaries in conversation about the Shared Savings Program and their ability to decline to share their own health data at the beneficiaries' first primary care visit.

We believe this modification will continue to afford beneficiaries with a meaningful choice about the sharing of their claims data, while also allowing practitioners to have more timely access to beneficiaries' claims data in order to begin coordinating care for those beneficiaries as soon as possible. This additional flexibility may be particularly important in the case of beneficiaries who do not schedule an appointment with a primary care practitioner until later in the year or not at all in a given year. As noted previously, under § 425.704(b) ACOs should not continue to request claims data for beneficiaries that the ACO knows are no longer being treated by ACO participants or who have not been assigned to the ACO during the retrospective reconciliation.

Final Decision: We will finalize our proposal in § 425.704, to allow ACOs to request beneficiary identifiable data on a monthly basis.

Additionally, we are modifying this proposal in § 425.708 to allow the ACO the option of contacting beneficiaries from the list of preliminarily prospectively assigned beneficiaries in order to notify them of the ACO's participation in the program and their intent to request beneficiary identifiable data. If, after a period of 30 days from the date the ACO provides such notification, neither the ACO nor CMS has received notification from the beneficiary to decline data sharing, the ACOs would be able to request beneficiary identifiable data. The ACO would be responsible for repeating the notification and opportunity to decline sharing information during the next face-to-face encounter with the beneficiary in order to ensure transparency, beneficiary engagement, and meaningful choice.

We note that if a beneficiary declines to have their claims data shared with the ACO, this does not preclude physicians from sharing medical record information as allowed under HIPAA amongst themselves, for example, a referring primary care physician providing medical record information to a specialist.

E. Assignment of Medicare Fee-for-Service Beneficiaries

Section 1899(c) of the Act requires the Secretary to ''determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A). Subsection 1899(h)(1)(A) constitutes one element of the definition of the term ''ACO professional.'' Specifically, this subsection establishes that ''a physician (as defined in section 1861(r)(1))'' is an ''ACO professional'' for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term 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 an ACO professional to include practitioners described in section 1842(b)(18)(C)(i) of the Act, such as PAs and NPs.

Assigning Medicare beneficiaries to ACOs also requires several other elements: (1) An operational definition of an ACO (as distinguished from the formal definition of an ACO and the eligibility requirements that we discuss 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; (2) a definition of primary care services for purposes of determining the appropriate assignment of beneficiaries; (3) a determination concerning 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; and (4) a determination concerning 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.

The term ''assignment'' in this context refers only to an operational process by which Medicare will determine 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, the ACO will then be 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 implement. It is important to note that the term ''assignment'' for purposes of this provision in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise complete freedom of choice in the physicians and other health care practitioners and suppliers from whom they receive their services.

Thus, while the statute refers to the assignment of beneficiaries to an ACO, we would characterize the process more as an ''alignment'' of beneficiaries with an ACO, that is, the exercise of free choice by beneficiaries in the physicians and other health care providers and suppliers from whom they receive their services is a presupposition of the Shared Savings Program. Therefore, an important component of the Shared Savings Program will be timely and effective communication with beneficiaries concerning the Shared Savings Program, their possible assignment to an ACO, and their retention of freedom of choice under the Medicare FFS program. The issues of beneficiary information and communications are further discussed in section II.H.2.a. of this final rule.

Comment: A commenter noted that CMS experiences savings on Medicare Cost Contract products when admissions are avoided, but the value this generates is not currently shared by providers. The commenter noted that, in a Medicare Cost Contract, health plans assume risk for Part B services while CMS retains the risk for Part A services. In the PGP demonstration, the commenter's organization created savings for both Medicare FFS and Cost Contract patients, and CMS received the benefit of reduced hospital admissions. These savings were not calculated into the gain sharing arrangement within the PGP demonstration program nor could they be recognized in cost plan contracts since the value accrued solely to CMS. The commenter believed that this disconnect makes it cost prohibitive to invest in technologies to improve care across our senior patient population. CMS should include these patients in

the performance calculations for ACOs with a significant Cost Contract population''

Response: We assume that the commenter is referring to cost contracts which exist under section 1876 of the Act. Section 1899(h)(3) of the Act defines a ''Medicare fee-for-service beneficiary'' for purposes of the Shared Savings Program as ''an individual who is enrolled in the original Medicare fee-for-service program under parts A and B and is not enrolled in an MA plan under part C, an eligible organization under section 1876, or a PACE program under section 1894.'' Therefore, the statute precludes assignment of cost contract beneficiaries to ACOs under the Shared Savings Program.

Comment: Another commenter cited the definition of ''Medicare fee-for-service beneficiary'' under section 1899(h)(3) of the Act, but then requested that Medicare beneficiaries that can participate in the ACO should include Seniorcare enrollees. The commenter describes ''Seniorcare'' as a product for Medicare beneficiaries which falls under section 1876 of the Act, and contends that their participation in an ACO should be permitted because they represent a small population that is ''important in rural areas.'' Finally, the commenter contends that dual eligibles should be included in the program, observing that their participation in the Shared Savings Program would require coordination with the States, and suggesting that we gather data on the dual eligibles who participate during the first years of the MSSP in order to determine whether any issues arise with their participation.

Response: As we have discussed previously, section 1899(h)(3) of the Act specifically excludes individuals ''enrolled in an eligible organization under section 1876'' from the definition of ''Medicare fee-for-service beneficiary'' for purposes of the Shared Savings Program. The commenter stated that Seniorcare is a Medicare product offered under section 1876 of the Act. Seniorcare enrollees therefore may not be assigned to an ACO. Nothing in section 1899 of the Act, however, precludes assignment of dual eligibles enrolled in the original Medicare FFS program to ACOs participating in the Shared Savings Program. CMS' goal is to promote complete integration of care provided and align incentives for all individuals whether under Medicare, Medicaid, or both. We agree with the commenter's suggestion that we carefully monitor ACO care coordination, quality of care, and costs for dual eligibles including the impact on Medicaid and will implement this within our monitoring plans. In addition, we intend to study the effect of assignment of dually eligible individuals to ACOs in the MSSP on Medicaid expenditures, and may use this information in the development of future models for testing by the Innovation Center.

Final Decision: We are finalizing our proposed policies concerning the eligibility of Medicare FFS beneficiaries for assignment to an ACO under the Shared Savings Program. Specifically, as required by the statute, and consistent with the definition of Medicare fee-for-service beneficiary in § 425.20, under § 425.400(a) only individuals enrolled in the original Medicare fee-for-service program under parts A and B, and not enrolled in an MA plan under Part C, an eligible organization under section 1876 of the Act, or a PACE program under section 1894 of the Act, can be assigned to an ACO.

1. Definition of Primary Care Services

Section 1899(c) of the Act requires the Secretary to assign beneficiaries to an ACO ''based on their utilization of primary care services'' provided by a physician. However, the statute does not specify which kinds of services should be considered ''primary care services'' for this purpose, nor the amount of those services that would be an appropriate basis for making assignments. We discuss issues concerning the appropriate proportion of such services later in the final rule. In this section of this final rule, we discuss how to identify the appropriate primary care services on which to base the assignment and our final policy for defining primary care services for this purpose.

In the proposed rule, we proposed to define ''primary care services'' as a set of services identified by these HCPCS codes: 99201 through 99215; 99304 through 99340; and 99341 through 99350. Additionally, we proposed to consider the Welcome to Medicare visit (G0402) and the annual wellness visits (G0438 and G0439) as primary care services for purposes of the Shared Savings Program.

Comment: One commenter expressed concern that an assignment methodology based on primary care services could lead to an unintended negative consequence: ''An attribution model based on primary care utilization could result in a disproportionate number of high-risk beneficiaries, as compared to low-risk beneficiaries, being assigned to the ACO. Low-risk beneficiaries may be less likely to have visited a PCP or other physician, resulting in that patient not being assigned to an ACO. Therefore, the commenter encourages CMS to consider ways in which these beneficiaries can be encouraged to seek preventive care and become involved in an ACO.

Response: We disagree that an attribution model based on primary care utilization could result in a disproportionate number of high-risk beneficiaries being assigned to the ACO. Many low risk beneficiaries still visit a PCP or other physician once or twice a year for routine check-ups and assessments. Furthermore, we are bound by the statutory requirement that assignment be based upon the utilization of primary care services rendered by a physician. Nevertheless, we will keep this concern in mind as we implement the Shared Savings Program and gain experience in its operation during its first few years.

Comment: One commenter requested that the code sets used to determine assignment include inpatient evaluation and management (E&M) code: ''Observation—99218–99220/Initial, 99224–99226/Subsequent; Hospital Inpatient—99221- 99223/Initial, 99231–99233/Subsequent; and Hospital Inpatient Consultation—99251–99255.'' Another recommended excluding hospital emergency visits and urgent care visits. Another commenter noted that the proposed rule narrowly defines ''primary care services,'' and expressed uncertainty about how we envision the organization of care such as occupational therapy within the proposed ACO framework. Specifically, the commenter asked whether only E&M codes will be used to determine the plurality of care, or whether the provision of other services will also be considered. Or will these other services only be considered in terms of savings?

A national association recommended that certain CPT codes for remote monitoring and care coordination be used in the assignment process without being tied to a physician office visit. Another association expressed concern that the method for assigning beneficiaries should account for the patients receiving care in post-acute settings, where the providers may not fall within the proposed definition of primary care physician. One commenter argued that the inclusion of skilled nursing facility (SNF) and home visit CPT codes would be problematic for some systems because an ACO could potentially provide the plurality of outpatient care in an office setting to a beneficiary and yet the beneficiary still might not be assigned to that ACO. The commenter noted that this would happen in the case where a beneficiary is hospitalized and then discharged to a

nursing home not affiliated with the ACO physicians. In the view of the commenter, this method would not result in the alignment of the beneficiary with the correct provider. Another commenter noted that groups that have providers practicing in skilled nursing facilities are often assigned patients who have many visits over a short period of time in those facilities, but who are not their primary care patients.

Response: We proposed the list of codes that would constitute primary services for two reasons. First, we believed the proposed list represented a reasonable approximation of the kinds of services that are described by the statutory language (which refers to assignment of ''Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services''). 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. That section establishes an incentive program 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 Shared Savings Program. We have slightly expanded the list 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 for purposes of the Shared Savings Program. These codes clearly represent primary care services frequently received by Medicare beneficiaries, and in the absence of the special G codes they would be described by one or more of the regular office visit codes that we have adopted from section 5501 of the Affordable Care Act. Finally, the statute requires that assignment be based upon the utilization of primary care services by physicians. For this reason, only primary care services can be considered in the assignment process. Other services can, as one commenter noted, only be considered in terms of determining shared savings, if any.

With regard to the comments about the inclusion or exclusion of certain codes, we would observe first that the codes for hospital emergency visits (99281 through 99288) and urgent care visits (we assume the commenter refers to 99291 and 99292, which represent critical care services) were not included in our proposed list of codes representing primary care services. We believe that the inclusion of the codes for SNF visits is appropriate because beneficiaries often stay for long periods of time in SNFs, and it is reasonable to conclude that these codes represent basic evaluation and management services that would ordinarily be provided in physician offices if the beneficiaries were not residing in nursing homes. Inpatient hospital visit codes (99221 through 99223), in contrast, are intrinsically related to the acute care treatment of the specific condition or conditions that required the inpatient hospital stay, and we therefore do not believe that these codes represent the kind of general evaluation and management of a patient that would constitute primary care. Finally, we would observe in general that it would be impossible to establish a list of primary care codes by considering all of the ways in which the inclusion, or exclusion, of certain codes or sets of codes would advantage or disadvantage different types of potential ACOs. The code set that we are adopting in this final rule represents the best approximation of primary care services based upon relevant precedents and the information we currently have available. However, we intend to monitor this issue and will consider making changes to add (or delete) codes, if there is sufficient evidence that revisions are warranted.

Final Decision: We are finalizing our proposal to define ''primary care services'' in § 425.20 as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439) as primary care services for purposes of the Shared Savings Program. In addition, as we will discuss later in this final rule, in this final rule we will establish a cross-walk 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 ACO assignment process.

a. Consideration of Physician Specialties in the Assignment Process

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.

In developing our proposal, we considered three options with respect to defining ''primary care services'' for the purposes of assigning beneficiaries under the Shared Savings Program: (1) Assignment of beneficiaries based upon a predefined set of ''primary care services;'' (2) assignment of beneficiaries based upon both a predefined set of ''primary care services'' and a predefined group of ''primary care providers;'' and (3) assignment of beneficiaries in a step-wise fashion. Under the third option, beneficiary assignment would proceed by first identifying primary care physicians (internal medicine, family practice, general practice, geriatric medicine) who are providing primary care services, and then identifying specialists who are providing these same services for patients who are not seeing any primary care physician.

We proposed to assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries. As discussed previously, we proposed to define ''primary care services'' on the basis of the select set of HCPCS codes identified in the section 5501 of the Affordable Care Act, including G-codes associated with the annual wellness visit and Welcome to Medicare visit. We made this proposal in the belief that this option best aligned with other Affordable Care Act provisions related to primary care by placing an appropriate level of emphasis on a primary care core in the Shared Savings Program. That is, we believed that the proposed option placed priority on the services of designated primary care physicians (for example, internal medicine, general practice, family practice, and geriatric medicine) in the assignment process. The option is also relatively straightforward administratively.

However, we expressed our concern that this proposal might not adequately account for primary care services delivered by specialists, especially in certain areas with shortages of primary care physicians, and that it may make it difficult to obtain the minimum number of beneficiaries to form an ACO in geographic regions with such primary care shortages. Therefore, while we proposed to assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries, we invited comment on this proposal and other options that might better address the delivery of primary care services by specialists, including a ''step-wise approach'' under which beneficiaries could be assigned to an ACO based upon primary care services furnished by a specialist if they do not have any visits with a primary care physician.

Comment: We received some very strong comments supporting our exclusion of services provided by

specialists in the assignment process, especially from organizations representing primary care physicians and from individual primary care physicians. Some endorsed our proposal because it ''supports the intent of the ACA for primary care practitioners to reduce the fragmentation of care and improve overall quality. Many specialists are not providing the primary, preventive services that are the building blocks for ACOs. Rather, specialists may tend to be quicker to refer patients to other specialists for problems outside the scope of their practice.'' Several other comments even urged CMS to tighten the definition of primary care services by specifying ''general internal medicine'' rather than ''internal medicine'' to ensure that Medicare ACOs are truly based on primary care physicians. One commenter also noted the absence of ''measures of physician competence or capability'' in a rule with an abundance of requirements in many areas. Another commenter urged that we include preventive medicine physicians under the definition of primary care or the definition of general practice. Another recommended that, rather than list ''primary care services,'' CMS go further to state that the primary care professionals be limited to those eligible for Primary Care Incentive Payments under section 5501 of the Affordable Care Act as a matter of consistency and specificity across CMS policy. This commenter maintained that specialists are not providing continuing and comprehensive primary healthcare to their patients, and the commenter thus opposed any further expansion of the definition of ''primary care professional'' for purposes of assigning patients to ACOs.

However, many commenters, including specialty societies, major medical centers, and others, strongly advocated inclusion of primary care codes from specialist physicians in the assignment process. Among other points, these commenters cited the shortages of primary care physicians in some areas. Others cited the fact that patients with certain chronic conditions (for example, diabetes, cardiac conditions, persons with disabilities, etc.) do receive most of their primary care from the specialist treating their conditions. One commenter raised the concern that the proposed definition of primary care services may not adequately represent services provided in post-acute care settings such as long-term care hospitals (LTCHs). The commenter noted that many LTCH patients are seen by teams of specialists who provide the bulk of the actual primary care services to these patients who often do not have a primary care physician. Other commenters also advocated including specialists in order to allow the formation of condition-specific ACOs, such as ''renal-focused ACOs.'' One physician society advocated expanding the definition of primary care, but retaining some limitations related to the specialty of the physicians providing services designated by the HCPCS basic office visit codes, on the grounds that subspecialty physicians often fulfill the primary care needs of their patients. This commenter and others cited subspecialty areas such as nephrology, oncology, rheumatology, endocrinology, pulmonology, and cardiology that might frequently be providing primary care to their patients.

Another commenter recommended that the specialties designated as providing primary care services be expanded to include certain specialties, but only if the ACO demonstrates, based on its own data of the assigned beneficiaries, that those specified specialist physicians are indeed providing primary care services on a regular and coordinated basis and the ACO is primary care focused and comprised of at least 30 percent primary care physicians and a maximum of 70 percent specialists. The commenter also argued that specialist-only group practices should not be eligible to become an ACO.

One commenter argued that the exclusion of specialists from the assignment process is contrary to the intent of the statute by noting that subsection 1899(h)(1)(A) of the Act defines an ''ACO professional'' for purposes of assignment as a physician as that term is defined in 1861(r)(1) of the Act—in other words, as an M.D. or a D.O. The commenter maintains that it is not an oversight that neither section 1861(r)(1) or 1899(c) of the Act mention physician specialty. The commenter also cites the Ways & Means report on section 1301 of H.R. 3200, the House predecessor to section 3022 of the Affordable Care Act, which codified the Shared Saving Program at section 1899 of the Act, which states: ''The Committee believes that physicians, regardless of specialty, who play a central role in managing the care of their patient populations, and who are willing and able to be held accountable for the overall quality and costs of care for their patients across all care settings, should be allowed to form ACOs.''

In order to account for the provision of many primary care services by specialists to chronically ill and other patients, one commenter suggested that the more appropriate method would be for the ACO to notify CMS who their ''Primary Care Providers'' are for an intended population within the ACO. In this way CMS can understand how to assign a beneficiary and a patient can know who their primary care' physician is within the ACO. Another commenter recommended allowing assignment to certain specialists (nephrology, rheumatology, endocrinology, pulmonology, neurology, and cardiology) provided the Medicare beneficiary has other primary care services for E&M Codes of less than 10 percent. One specialty society offered this alternative definition of primary care in support of considering pediatricians as primary care physicians for purposes of assignment: ''Primary health care is described as accessible and affordable, first contact, continuous and comprehensive, and coordinated to meet the health needs of the individual and the family being served.''

But one commenter maintained that the definition of primary care services should be less focused on the specialty of the provider, recommending that we should define primary care services by the services themselves, and then define primary care practitioners as those practitioners who primarily bill those services.

Of the commenters advocating inclusion of specialists in the assignment methodology, most recommend the option which assigns beneficiaries based on the plurality of primary care services regardless of specialty, although some would accept a variation that excludes those specialties that rarely provide primary care. One comment said that, while they do not believe it is ideal, they could also accept the hybrid model, in which the beneficiary is assigned to a specialist if not otherwise assigned to a primary care physician. The commenter emphasized that, if this option is selected, it would be important to ensure the primary care physician is in fact serving as the beneficiary's principal care provider. A number of other commenters, including MedPAC, recommended that, in the final rule, we adopt the step-wise approach that we discussed as an option in the proposed rule. Another commenter agreed that beneficiaries with at least one visit with a primary care physician (general practice, internists, family medicine or geriatrician as defined by CMS) should be assigned to an ACO based on their utilization of primary care services.

Response: We agree with the commenters who supported our proposal that the Shared Savings

Program should place a strong emphasis on primary care, which is consistent with the statutory requirement that assignment be based on the utilization of primary care services furnished by a physician. However, we cannot agree with those commenters who recommended that we tighten the definition of primary care services for purposes of the Shared Savings Program. For example, we do not agree with the recommendation of a few commenters that we include only ''general internal medicine'' rather than ''internal medicine'' under the proposed definition of primary care physician because the Medicare enrollment and billing systems contain a specialty code (specialty code 11) only for ''internal medicine,'' and we thus have no way to differentiate ''internal medicine'' from ''general internal medicine.'' On the merits, we also doubt that the specialty designations of ''internal medicine'' and ''general internal medicine'' selected by physicians reflect an adequate distinction between internal medicine specialists who primarily deliver primary care services and those who do not. (In addition, as we discuss later in this final rule, we have decided to include the primary care services provided by specialist physicians in the assignment process as part of the step-wise approach that we described in the proposed rule. As a result, to some degree, at least, the distinction between ''general internal medicine'' and ''internal medicine'' has become less significant, since both would be included in our new assignment methodology in any case.) We do not agree with the suggestion to add the designation of ''preventive care specialist'' to our list of primary care physicians, because as much as possible we are following the designations of primary care physicians established under section 5501 of the Affordable Care Act, which does not include this specialty. We also believe that it would be operationally complex, and perhaps overly onerous and restrictive to potential participants in the Shared Savings Program, to incorporate special competency standards into the definition of primary care physician.

We do not agree with commenters who argued that our proposed restriction of primary care services to those provided by primary care physicians was contrary to the statute. Section 1899 of the Act does not specifically define the term ''primary care services.'' Furthermore, section 1899(c) of the Act gives the Secretary discretion to determine ''an appropriate method'' to assign beneficiaries based on their utilization of primary care services furnished by a physician affiliated with the ACO, and thus allows the Secretary broad discretion in defining the term ''primary care.'' We would also note that our proposed definition largely followed the precedent established by section 5501(a) of the Affordable Care Act, the provision governing primary care incentive payments, and is thus clearly consistent with the overall intent of that Act, which also establishes the Shared Savings Program.

However, in the proposed rule we also expressed some concerns about the possible effects of the proposed policy in eliminating certain genuine primary care services from consideration in the assignment process. In particular, we noted our concern about possibly excluding primary care services delivered by specialists, especially in some areas with shortages of primary care physicians, where specialists necessarily deliver the bulk of primary care services. We also noted that, especially for beneficiaries with certain conditions (for example, heart conditions and diabetes), specialist physicians often take the role of primary care physicians in the overall treatment of the beneficiaries. The commenters have confirmed these concerns, and persuaded us that, in the end, the Shared Savings Program should not restrict assignment purely to a defined set of primary care services provided only by the specialties that can be appropriately considered primary care physicians. We agree that our proposed assignment methodology would be unduly restrictive in areas with shortages of primary care physicians. We also agree that specialists do necessarily and appropriately provide primary care services for many beneficiaries with serious and/or chronic conditions.

Therefore, in this final rule we are adopting a more balanced assignment process that simultaneously maintains the primary care-centric approach of our proposed approach to beneficiary assignment, while recognizing the necessary and appropriate role of specialists in providing primary care services. As we previously noted, in the proposed rule we discussed a step-wise approach to beneficiary assignment. Under this approach, after identifying all patients who had a primary care service with a physician at the ACO, beneficiary assignment would proceed by first identifying primary care physicians (internal medicine, family practice, general practice, geriatric medicine) who are providing primary care services, and then identifying specialists who are providing these same services for patients who are not seeing any primary care physician. We hesitated to propose this option because we were concerned that it would introduce a greater level of operational complexity compared to the two other options we considered. In addition, we were concerned that it could undermine our goal of ensuring competition among ACOs by reducing the number of specialists that can participate in more than one ACO, since the TINs of specialists to whom beneficiaries are assigned would be required to be exclusive to one ACO. (As noted in section II.B.1.d of this final rule, the TINs upon which assignment is based must be exclusive to one ACO for purposes of participation in the Medicare Shared Savings Program. However, exclusivity of an ACO participant to one ACO is not necessarily the same as exclusivity of individual practitioners to one ACO. For example, exclusivity of ACO participants leaves individual NPIs free to participate in multiple ACOs if they bill under several different TINs. The ability of individual specialists to participate in more than one ACO is especially important in certain areas of the country that might not have many specialists.) On the other hand, we acknowledged that a ''step-wise approach'' would reflect many of the advantages of the other two approaches we discussed in the proposed rule (including the option we proposed), balancing the need for emphasis on a primary care core with a need for increased assignment numbers in areas with primary care shortages. Despite our initial misgivings regarding this approach, we have come to agree with MedPAC and the other commenters who endorsed such an approach that it provides the best available balance of 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.

Final Decision: Under § 425.402, after identifying all patients that had a primary care service with a physician who is an ACO provider/supplier in an ACO, we will employ a step-wise approach as the basic assignment methodology. Under this approach, beneficiaries are first assigned to ACOs on the basis of utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians. This final policy thus

allows consideration of all physician specialties in the assignment process. We describe this step-wise approach in greater detail later in this final rule, after further addressing other related issues, including consideration of primary care services furnished by non-physician practitioners, such as NPs and PAs. As also discussed later in this final rule, we will also consider only the specific procedure and revenue codes designated in this final rule in the assignment process.

b. Consideration of Services Furnished By Non-Physician Practitioners in the Assignment Process

In the proposed rule we observed that, although the statute defines the term ''ACO professional'' to include both physicians and non-physician practitioners, such as physician assistants (PAs), and nurse practitioners (NPs), for purposes of beneficiary assignment to an ACO, the statute also requires that we base assignment on beneficiaries' utilization of primary care services provided by ACO professionals who are physicians. As we discussed previously, section 1899(c) of the Act requires the Secretary to ''determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A).'' Section 1899(h)(1)(A) of the Act constitutes one element of the definition of the term ''ACO professional.'' Specifically, this subsection establishes that ''a physician (as defined in section 1861(r)(1))'' is an ''ACO professional'' for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term 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''. Therefore, for purposes of the Shared Savings Program, the inclusion of practitioners described in section 1842(b)(18)(C)(i) of the Act, such as PAs and NPs, in the statutory definition of the term ''ACO professional'' is a factor in determining the entities that are eligible for participation in the program (for example, ''ACO professionals in group practice arrangements'' under section 1899(b)(1)(A) of the Act). However, we proposed that the assignment of beneficiaries to ACOs would be determined only on the basis of primary care services provided by ACO professionals who are physicians.

Comment: We received numerous comments, especially from individual practitioners and organizations representing nurses, PAs, and others, objecting to the exclusion of primary care services provided by NPs, certified nurse midwives, other nursing practitioners, PAs and other non-physician practitioners from the assignment process. Many NPs and nurse associations commented that the ''limitation will significantly impair the ability of patients to access primary care services. It will negatively affect not only access, but the cost and quality of the care provided by the ACOs.'' The commenters emphasized that NPs have a long history of providing high quality, cost effective care and that their skills in the area of care coordination, chronic disease management, health promotion, and disease prevention could contribute significantly to the quality and cost savings of any shared saving program. Some commenters urged that CMS should take any opportunity it has to encourage the use of non-physician providers in the care of Medicare beneficiaries.

Commenters advocated several approaches to dealing with the statutory language under which assignment turns on primary care services provided by ''an ACO professional described in subsection (h)(1)(A),'' which specifies ''* * * a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action.'' Some commenters argued that the reference to ''subsection (h)(1)(A)'' represents a drafting error, and that that we should proceed on the assumption that the reference should have been to ''subsection (h)(1),'' which includes not only physicians, but also CNSs, NPs, and PAs. Other commenters argued that it is not necessary to interpret the requirement that beneficiaries be assigned based on primary care services ''provided'' by a physician to mean that Medicare beneficiaries are to be assigned to ACOs solely based on services ''directly provided'' by a physician. These commenters maintained that the statute does not require that services be ''directly provided'' by a physician, but only that physicians provided care, which can be done directly or indirectly.

A national nurses' association and several other commenters acknowledged that the correct statutory reference concerning assignment is to ''subsection (h)(1)(A),'' which allows assignment only on the basis of physician services, but also argued that ''CMS can abide by the statutory requirement by basing assignment on utilization of primary care services provided by an ACO physician without requiring a plurality. Any primary care service provided by an ACO primary care physician should be enough to trigger assignment, as long as some other ACO participant has provided the plurality of primary care services to that beneficiary.''

PAs, their representative organizations, and some other commenters disagreed with the exclusion of PAs from the assignment process. One commenter was ''extremely disappointed'' that PAs are not included in the definition of primary care professional. Some commenters suggest that the discretionary authority provided to the Secretary of Health and Human Services under section 1899(i) of the Act allowing for the utilization of other payment models under the Shared Savings Program could provide the means to include non-physician practitioners such as PAs and NPs. Another commenter recommended that the care provided by a PA, pursuant to the criteria outlined in the proposed rule, be used to determine assignment to an ACO. Since PAs practice in a collaborative nature with physicians, the commenter believed it appropriate that beneficiaries who receive a plurality of primary care services from a PA be assigned based upon these services. However, they would also restrict recognition of care provided by non-physician providers only to those who have a collaborative or supervisory agreement with physicians, excluding some NPs who practice independently.

Response: We cannot agree with those commenters who maintained that the wording of section 1899(c) of the Act with respect to considering primary care services provided by physicians should be treated as a ''drafting error.'' We are unaware of any direct or indirect evidence that the reference to ''an ACO professional described in subsection (h)(1)(A)'' rather than to ''an ACO professional described in subsection (h)(1)'' was made in error. Even if there were convincing evidence to that effect, given the clarity of the plain language of the statute, it would not fall within our authority to correct that error. Therefore, in implementing the Shared Savings Program, the assignment methodology will be based on utilization of primary care services provided by physicians. At the same time, we agree with the many commenters who emphasized that NPs, PAs, and clinical nurse specialists (CNSs) have a well-established record of providing high quality and cost-effective care. We also agree that these practitioners can be significant assets to the ACO in the areas of quality and cost saving, and indeed that the appropriate use of NPs, PAs, and CNSs could be an important element in the success of an

ACO participating in the Shared Savings Program. As many commenters noted, the skills of these practitioners, especially in care coordination, chronic disease management, health promotion, and disease prevention certainly can contribute significantly to the quality and cost savings of any shared saving program. (We would note in this context that nothing in the statute precludes an ACO from sharing savings with NPs and other practitioners, whether or not their services are included in the assignment process.)

We also cannot agree with the commenters who suggested that the statutory language may be read to allow assignment to be based on services provided ''indirectly'' by a physician. Although the statute does not include the word ''directly,'' it does require that assignment be based on services ''provided'' by physicians. The statutory requirement that assignment be based on physician services, not services furnished by ACO professionals more generally, would be rendered meaningless if we were to adopt a reading of the statute that permits physician services to be furnished ''indirectly.'' For example, under this reading, a beneficiary could be assigned to an ACO without ever having seen a physician in the ACO. We believe that such an interpretation is directly contrary to the intent of section 1899(c) of the Act, and in particular, contrary to the express statutory requirement that assignment be based on physician services rather than ACO professional services, more generally.

However, we took special note of one comment cited previously, specifically the comment that: ''Any primary care service provided by an ACO primary care physician should be enough to trigger assignment, as long as some other ACO participant has provided the plurality of primary care services to that beneficiary.'' This commenter suggested that it may be possible to employ the discretion that is afforded to the Secretary under the statute to determine ''an appropriate method'' for assigning beneficiaries to an ACO based on the utilization of primary care services furnished by a physician by considering the receipt of physician primary care services as a triggering factor in the assignment process, prior to considering where the beneficiary has received a plurality of primary care services provided by the full range of ACO professionals, so that the beneficiary is appropriately assigned to the ACO which bears the primary responsibility for his or her primary care. Specifically, we could implement the statutory requirement that assignment be based on physician services, by assigning a beneficiary to an ACO if, and only if, the beneficiary has received at least one primary care service from a physician who is an ACO provider/supplier in the ACO. Therefore, as required by the statute, we would be assigning beneficiaries to an ACO based upon the receipt of primary care from a physician in the ACO. However, we would apply this policy in the step-wise fashion that we have discussed previously, that is, basing assignment in a first step on the primary care services provided by primary care physicians (measured in terms of allowed charges) alone. Then, in a second step, we would assign patients who are not seeing any primary care physician either inside or outside the ACO if they have received at least one primary care service from an ACO physician (of any specialty) in the ACO, and taking into account the allowed charges for primary care services provided by all ACO professionals in the ACO. The beneficiary will be assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers in any other ACO and allowed charges for primary care services furnished by physicians, NPs, PAs, and CNSs, who are not affiliated with an ACO. This method would avoid, for example, assignment of beneficiaries on the basis of receiving a few primary care services from specialist physicians, even though the beneficiary may be receiving the plurality of primary care services from specialist physicians, NPs or PAs who are ACO providers/suppliers in a different ACO.

In adopting this policy, we are also extending the policy regarding exclusivity of TINs on which assignment is based to one ACO: that is, the TINs under which the services of specialists, PAs, and NPs are included in the assignment process subsequent to the identification of the ''triggering'' physician primary care services would have to be exclusive to one ACO for purposes of the Shared Savings Program. (We emphasize that we are establishing this policy for purposes of Shared Savings Program ACOs only: commercial ACOs may or may not wish to adopt a similar policy.)

Comment: We received many comments from chiropractors and chiropractor associations recommending that the definition of ACO professional for purposes of the Shared Savings Program should be expanded to include chiropractors. These commenters cited the quality and cost efficiency of chiropractic services, and many also cited other statutory definitions of ''physician'' as precedents for including chiropractors within the definition of ''physician'' under the Shared Savings Program.

Response: We recognize that some other Federal and State laws include chiropractors within the definition of physician for various purposes. However, we are unable to consider services furnished by chiropractors in the assignment process under the Shared Savings Program. As previously explained, section 1899(c) of the Act requires that assignment be based upon ''utilization of primary care services provided * * * by an ACO professional described in subsection (h)(1)(A).'' Section 1899(h)(1)(A) of the Act defines an ''ACO professional'' as a physician (as defined in section 1861(r)(1) of the Act), which includes ''* * * a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action,'' but does not include chiropractors. Therefore, because chiropractors are not ACO professionals under section 1899(h)(1)(A) of the Act, we are unable to consider their services in the assignment process under the Shared Savings Program. However, it is important to note that this restriction certainly does not preclude Medicare-enrolled chiropractors from participating in ACOs, or from sharing in the savings that an ACO may realize in part because of the quality and cost-effective services they may be able to provide.

Final Decision: Therefore, under § 425.402 of this final regulation we are adopting the following step-wise process for beneficiary assignment. Our final step-wise assignment process takes into account the two decisions that we have just described: (1) Our decision to base assignment on the primary care services of specialist physicians in the second step of the assignment process; and (2) our decision also to take into account the plurality of all primary care services provided by ACO professionals in determining which ACO is truly responsible for a beneficiary's primary care in second step of the assignment process. Our final step-wise assignment process will thus occur in the following two steps, after identifying all patients that received a primary care service from a physician who is a provider/supplier in the ACO (and who are thus eligible for assignment to the ACO under the statutory requirement to base

assignment on ''utilization of primary care services''):

Step 1: We will identify beneficiaries who had received at least one physician primary care service from a primary care physician who is a provider/supplier in an ACO. In this step, a beneficiary can be assigned to an ACO only if he or she has received at least one primary care service from a primary care physician who is an ACO provider/supplier in the ACO during the most recent year (for purposes of preliminary prospective assignment, as discussed later in this final rule), or the performance year (for purposes of final retrospective assignment). If this condition is met, the beneficiary will be assigned to the ACO if the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of that ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of other ACOs, and greater than the allowed charges for primary care services provided by primary care physicians who are unaffiliated with any ACO (identified by Medicare-enrolled TINs or other unique identifiers, as appropriate).

Step 2: This step would consider only beneficiaries who have not received any primary care services from a primary care physician either inside or outside the ACO. Under this step a beneficiary will be assigned to an ACO only if he or she has received at least one primary care service from any physician (regardless of specialty) in the ACO during the most recent year (for purposes of preliminary prospective assignment), or the performance year (for purposes of final retrospective assignment). If this condition is met, the beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers of that ACO (including specialist physicians, NPs, PAs, and CNSs), are greater than the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers of each other ACO, and greater than the allowed charges for primary care services furnished by any other physician, NP, PA, or CNS, (identified by Medicare-enrolled TINs or other unique identifiers, as appropriate) who is unaffiliated with any ACO.

c. Assignment of Beneficiaries to ACOs That Include FQHCs and/or RHCs

In the proposed rule, we also considered the special circumstances of FQHCs and RHCs in relation to their possible participation in the Shared Savings Program. (For purposes of this discussion, all references to FQHCs include both section 330 grantees and so-called ''look-alikes,'' as defined under § 405.2401 of the regulations.) Our proposed methodology was to assign beneficiaries to an ACO if they receive a plurality of their primary care services (which we proposed to identify by a select set of E&M services defined as ''primary care services'' for other purposes in section 5501 of the Affordable Care Act, and including the G-codes associated with the annual wellness visit and Welcome to Medicare visit) from a primary care physician (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine) affiliated with the ACO. Thus, under the proposal, we would need data that identify the precise services rendered (that is, primary care HCPCS codes), type of practitioner providing the service (that is, a physician as opposed to NP or PA), and the physician specialty in order to be able to assign beneficiaries to the entities that wish to participate in the Shared Savings Program.

In general, FQHCs and RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all-inclusive rate. These claims distinguish general classes of services (for example, clinic visit, home visit, mental health services) by revenue code, the beneficiary to whom the service was provided, and other information relevant to determining whether the all-inclusive rate can be paid for the service. The claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, or NP) who provided the service. (Starting in 2011, FQHC claims are required to include HCPCS codes that identify the specific service provided, in order for us to develop a statutorily required prospective payment system for FQHCs.) In the proposed rule, we indicated that we did not believe we had sufficient data in order to assign patients to ACOs on the basis of services furnished by FQHCs or RHCs. Instead, recognizing the important primary care role played by these entities, we proposed to provide an opportunity for an ACO to share in a greater percentage of any savings if FQHCs/RHCs are included as ACO participants.

Comment: Many commenters disagreed with our interpretation of the statute's assignment provision (section 1899(c) of the Act) to require a patient to be assigned to an ACO based solely on that beneficiary's use of services furnished by specific categories of primary care physicians. These commenters encouraged CMS to explore other approaches that would allow FQHCs and/or RHCs to independently form ACOs and to take on a more active role in the ACO by allowing assignment of beneficiaries and establishment of benchmarks to be based upon services furnished by these entities.

MedPAC commented that it would be more straightforward to allow assignment of patients to RHCs and FQHCs and encourage their use directly rather than to introduce special provisions for the savings share and thresholds as the proposed rule does. They indicated that ''these are primary care provider teams often associated with a physician and usually providing primary care services. Logically they should be allowed to participate in ACOs and patients should be assigned to them. In many rural areas, RHCs function as primary care physicians' offices and, although they are paid differently under Medicare, they are still fulfilling the same function''. MedPAC suggested that ''CMS posit that all claims in RHCs and FQHCs are for primary care services and use them for assignment as it would any other primary care claim.''

Similarly, other commenters requested that CMS simply deem all FQHC services as primary care services. Other commenters believed it is more than reasonable to—and detrimental to the program's goals not to—interpret 1899(c) of the Act to find that the ''provided under'' language means not only services provided by the physician personally but also services provided by additional members of the health care team of an FQHC, with whom physicians supervise and collaborate. In short, they believed that the Secretary has the discretion to determine for purposes of patient assignment that patients who receive care from FQHCs can be treated as patients whose care is furnished by physicians since physician services are an integral part of the FQHC service definition, FQHC practice, and FQHC reimbursement.

Other commenters suggested that CMS could assign FQHC beneficiaries to ACOs in other ways. Specifically, a commenter indicated that the UB–04 billing form that FQHCs use to submit their claims contains sufficient information (for example, patient information, revenue codes, and ''attending physician'' information) to establish a reasonable process for assigning FQHC beneficiaries to ACOs. This commenter also noted that these health centers have a limited set of services that are considered ''FQHC

services'' and that virtually all such services would be considered primary care services.

Another commenter indicated that all FQHCs and RHCs should have the capability to provide additional information about their services beyond the information available on their claims. The commenter stated that to be covered for a malpractice claim, a health care center must be able to demonstrate (through appropriate documentation) that the services at issue were within the center's scope of services, provided at a location that was in the scope of services, were delivered to an established patient of the health center, were documented in a permanent medical record and were properly billed. This commenter categorically stated that the necessary information is available, that it is electronic, and that it can be correlated with contemporaneous claims data.

Other commenters suggested that CMS consider other assignment approaches, such as the methodology it is using to attribute Medicare patients to FQHCs in the Adirondack Regional Medical Home Pilot, an all-payer medical home demonstration project in upstate New York.

Yet other commenters suggested that assignment could be made by an FQHC providing a list of patients for whom it considers itself accountable. CMS could then analyze the claims history for the identified patients and exclude those with a plurality of primary care services associated with a provider other than the FQHC.

Regarding RHCs, a number of commenters agreed that when a clinic submits the claim form, it is not required to identify the specific provider who rendered the service. They conceded that the RHC service could have been provided by a physician, a PA or an NP (and in some circumstances, a nurse midwife). These commenters suggested various ways to address this: (1) Require RHCs that are part of an ACO to identify the rendering provider on their claim form using the NPI of the rendering provider, and provide any other information needed through various means (similar to how quality data are submitted; and/or (2) use a patient attestation method for attributing/assigning RHC patients to the ACO.

Response: We agree with the many comments that FQHCs and RHCs should be allowed to participate in ACOs and have their patients assigned to such ACOs, provided that patients can be assigned in a manner that is consistent with the statute.

We indicated in the proposed rule that we would continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and consider whether it would be possible for Medicare beneficiaries to be assigned to an ACO on the basis of services furnished by an FQHC or RHC, thereby allowing these entities to have their Medicare beneficiaries included in the ACO's assigned population.

As indicated previously, MedPAC and some other commenters suggested that CMS posit or deem that all claims in RHCs and FQHCs are for primary care services and use them for assignment as it would any other primary care claim. We have not accepted these comments because they do not address the specific requirement in section 1899(c) of the Act which requires assignment of beneficiaries to an ACO based ''on their utilization of primary care services * * * by an ACO professional described in subsection (h)(1)(A).'' As discussed previously, section 1899(h)(1)(A) of the Act establishes that for the purposes of beneficiary assignment, an ''ACO professional'' is defined as a physician as defined in section 1861(r)(1) of the Act.

Likewise, we have not accepted other commenter suggestions that assignment could be made by an FQHC providing a list of patients for whom it considers itself accountable. Such an approach would also not be consistent with the statutory requirement that we develop an assignment process that is based on utilization of primary care services by an ACO professional, defined by the statute as a physician. We have also not adopted commenter suggestions that CMS should adopt the assignment processes that are being used in certain demonstration programs because these demonstration programs are not subject to the same statutory requirements that apply to this Shared Savings Program.

However, as explained later in this final rule, we are accepting suggestions from other commenters that, in combination, will enable us to adopt a policy in this final rule that will allow us to assign beneficiaries to ACOs on the basis of services furnished by FQHCs and/or RHCs. (As we have explained earlier in section II.B. (Eligible Entities) of this final rule, this will also allow FQHCs and RHCs to form an ACO independently, without the participation of other types of eligible entities. It will also allow the beneficiaries who receive primary care services from FQHCs and RHCs to count in the assignment process for any ACO that includes an FQHC and/or RHC as a provider/supplier.) As discussed previously, the assignment methodology we are adopting in this final rule is to assign beneficiaries to an ACO using a step-wise approach for assignment. Under this step-wise method, beneficiaries are first assigned to an ACO if they have received a primary care service from a primary care physician (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine) who is a provider/supplier in the ACO, and also receive a plurality of their primary care services (which we identify by a select set of E&M services defined as ''primary care services'' in section 5501 of the Affordable Care Act, and the G-codes associated with the annual wellness visit and the Welcome to Medicare visit) from primary care physicians who are providers/suppliers in the same ACO. Those beneficiaries who have not received any primary care services from a primary care physician can be assigned to an ACO in the second step if they have received a primary care service from a specialist physician (that is, a physician that does not meet the definition of a primary care physician) who is a provider/supplier in the ACO, and also receive a plurality of their primary care services from physicians and other ACO professionals who are ACO providers/suppliers in the ACO. Thus, under the final rule, in order to be able to align beneficiaries with the entities that wish to participate in the Shared Savings Program, in general we require data that identify all of the following:

- Services rendered (that is, primary care HCPCS codes).
- Type of practitioner providing the service (that is, a physician, NP, PA, or CNS).
- Physician specialty.

For services billed under the physician fee schedule, these data items are available on the claims submitted for payment. In contrast, as discussed in the proposed rule, FQHCs and RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all-inclusive rate. These FQHC/RHC claims distinguish general classes of services (for example, clinic visit, home visit, mental health services) by revenue code, the beneficiary to whom the service was provided, and other information relevant to determining whether the all-inclusive rate can be paid for the service. The claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, NP), who provided the service.

(1) Identification of Primary Care Services Rendered in FQHCs and RHCs

Starting in 2011, FQHC claims are required to include HCPCS codes that identify the specific service provided, in order for us to develop a statutorily required prospective payment system for FQHCs. In addition, FQHCs were required to submit a HCPCS code to receive payment for the Welcome to Medicare visit (G0402) beginning in 2009. Therefore, we can identify primary care services for FQHCs that are participating in an ACO by using their HCPCS codes for services furnished on or after January 1, 2011, and by using HCPCS code G0402 furnished on or after January 1, 2009. RHCs are generally not required to report HCPCS codes, except that: (1) For services furnished on or after January 1, 2009, RHCs may submit HCPCS code G0402 to receive payment for the Welcome to Medicare visit, and (2) for services furnished on or after January 1, 2011, RHCs may submit HCPCS codes to receive payment for the annual wellness visits (G0438 and G0439). However, for purposes of assigning patients and calculating the benchmark, we will also need to identify other primary care services that were furnished by FQHCs and RHCs. In order to identify primary care services rendered in FQHCs and RHCs that are primary care services, and that are not required to be reported by HCPCS codes, we are adopting the commenters' suggestions to use the revenue center codes. We have reviewed these revenue center codes and agree that for purposes of the Shared Savings Program, the revenue center codes can be used as a substitute for the primary care HCPCS codes which RHCs do not report, and which FQHCs were not required to report prior to January 1, 2011. Specifically, we believe that it is possible to employ these revenue codes to identify primary care services by constructing an appropriate cross-walk between the revenue center codes and the HCPCS primary care codes based on their definitions.

In order to establish such a cross-walk, we compared the HCPCS codes that are considered as being primary care services for purposes of the Shared Savings Program with the revenue center codes that are reported on FQHC/RHC claims. As discussed previously, the primary care HCPCs codes used for assignment are as follows:

- 99201 through 99215; (office/outpatient visits).
- 99304 through 99340; (nursing facility visits/domiciliary home visits).
- 99341 through 99350; (home visits).
- Welcome to Medicare visit (G0402).
- Annual wellness visits (G0438 and G0439).

FQHCs and RHCs report services on their claims using the following revenue center codes:

0521—Clinic visit by member to RHC/FQHC

0522—Home visit by RHC/FQHC practitioner

0524—Visit by RHC/FQHC practitioner to a member, in a covered Part A stay at the SNF

0525—Visit by RHC/FQHC practitioner to a member in an SNF (not in a covered Part A stay) or NF or ICF MR or other residential facility

We are able to cross walk the ''primary care'' HCPCS codes to comparable revenue center codes based on their code definitions. For example, HCPCS codes 99201 through 99215 (office/outpatient visits) will be cross-walked to revenue center code 0521. Because the focus of FQHCs and RHCs is on primary care, we believe these revenue center codes, when reported by FQHCs/RHCs, would represent primary care services and not more specialized care. This cross-walk will allow us to use the available revenue center codes as part of the beneficiary assignment process for FQHC/RHC services in place of the unavailable HCPCS codes which will be used more generally. We will establish and update this crosswalk through contractor instructions. For FQHCs, we will use the HCPCS codes which are included on their claims starting on January 1, 2011.

(2) Identification of the Type of Practitioner Providing the Service in an FQHC/RHC

Secondly, in order to be able to align beneficiaries with the entities that wish to participate in the Shared Savings Program, we also generally require data that identify the type of practitioner providing the service (that is, a physician, NP, PA, or CNS). This is because, as discussed previously, section 1899(c) of the Act requires that assignment must be based upon services furnished by physicians. As previously noted, FQHC/RHC claims contain limited information as to the type of practitioner providing a service because this information is not necessary to determine payment rates for services in FQHCs and RHCs.

Based upon our review of the many helpful comments we received on these issues, we now agree that we can develop a process that will allow FQHCs and RHCs to fully participate in the Shared Savings Program. We can do this by using the limited provider NPI information on the FQHC/RHC claims in combination with a supplementary attestation requirement. This would be consistent with comments we received encouraging us to identify the provider that furnished services in FQHCs/RHCs by using the NPI of the attending provider, supplemented by additional information that the FQHCs/RHCs could separately submit.

More specifically, from the FQHC/RHC claims, we will use the Attending Provider NPI field data which is defined as being: ''the individual who has overall responsibility for the patient's medical care and treatment reported in this claim/encounter.'' Although the attending provider NPI is used to report the provider who is responsible for overall care, it does not identify whether this provider furnished the patient care for the beneficiary. Therefore, to meet the requirement of section 1899(c) of the Act which requires that assignment must be based upon services furnished by physicians, we will supplement these limited claims data with an attestation that would be part of the application process for ACOs that include FQHCs/RHCs. We will require ACOs that include FQHCs/RHCs to provide to us, through an attestation, a list of their physician NPIs that provide direct patient primary care services, that is, the physicians that actually furnish primary care services in the FQHC or RHC. Other physician NPIs for FQHCs/RHCs will be excluded from the assignment process, such as those for physicians whose focus is on a management or administrative role. The attestation must be submitted as part of the application for ACOs that include FQHCs/RHCs. Such ACOs will also be required to notify us of any additions or deletions to the list as part of the update process discussed in section II.C.4. of this final rule. The attestation by the ACO will better enable us to determine which beneficiaries actually received primary care services from an FQHC/RHC physician.

We will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to us through the attestation process to identify and assign beneficiaries to ACOs that include FQHCs/RHCs using the step-wise assignment methodology as previously explained.

In this way, we would then be able to assign beneficiaries to ACOs on the basis of services furnished in FQHCs and RHCs in a manner consistent with how we will more generally assign primary care services performed by physicians as previously described. We believe this approach meets the statutory requirement in section 1899(c)

of the Act that assignment be based on the utilization of primary care services ''provided'' by an ACO professional described as a physician in section 1899(h)(1)(A) of the Act.

(3) Identification of the Physician Specialty for Services in FQHCs and RHCs

As previously explained, the third type of information we generally need under the step-wise assignment process discussed previously to assign beneficiaries with the entities that wish to participate in the Shared Savings Program is data that identify physician specialty. However, we agree with commenters who pointed out that the Medicare FQHC health benefit was established in 1991 to enhance the provision of primary care services in underserved urban and rural communities. Commenters pointed out that virtually all services provided under the Medicare FQHC benefit are primary care services. We also agree with commenters that RHCs predominantly provide primary care services to their populations. Therefore, when a physician provides a service in an FQHC or an RHC, we believe the physician is functioning as a primary care physician comparable to those physicians that define themselves with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine. As a result, we do not believe it is necessary to obtain more detailed specialty information (either through the claims NPI reporting or as part of the attestation process) for the physicians that furnish services in FQHCs and RHCs. Longer term, we will consider establishing definitions for data fields on the claims submitted by FQHCs and RHCs, such as for attending NPI or other NPI fields, which could be used to identify the type of practitioner providing the service. This may enable us to eliminate the attestation which will part of the application process for ACOs that include FQHCs/RHCs.

Final Decision: In § 425.404, we are modifying the policy that we proposed in response to comments to establish a beneficiary assignment process that will allow primary care services furnished in FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC and/or RHC. (These changes to the assignment process will also allow FQHCs and RHCs to form ACOs independently, without the participation of other types of eligible entities.) Operationally we will assign beneficiaries to ACOs that include FQHCs/RHCs in a manner consistent with how we will assign beneficiaries to other ACOs based on primary care services performed by physicians as previously described.

We will require that an ACO that include FQHCs and/or RHCs to provide us, through an attestation, with a list of the physician NPIs that provide direct patient primary care services in an FQHC or RHC. This attestation will be part of the application process for all ACOs that include FQHCs and/or RHCs as ACO participants. We will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to us through the attestation process to identify beneficiaries who receive a primary care service in an FQHC or RHC from a physician, and to assign those beneficiaries to the ACO if they received the plurality of their primary care services, as determined based on allowed charges for the HCPCS codes and revenue center codes listed in the definition of primary care services, from ACO providers/suppliers.

2. Prospective vs. Retrospective Beneficiary Assignment To Calculate Eligibility for Shared Savings

Section 1899(d)(1) of the Act provides that an ACO may be eligible to share savings with the Medicare program if the ACO meets quality performance standards established by the Secretary (which we discuss in section II.F. of this final rule) and meets the requirements for realizing savings for its assigned beneficiaries against the benchmark established by the Secretary under section 1899(d)(1)(B) of the Act. Thus, for each performance year during the term of the ACO's participation agreement, the ACO must have an assigned population of beneficiaries. Eligibility for shared savings will be based on whether the requirements for receiving shared savings payments are met for this assigned population. In the proposed rule, we discussed two basic options for assigning beneficiaries to an ACO for purposes of calculating eligibility for shared savings during a performance year. The first option is that beneficiary assignment could occur at the beginning of the performance year, or prospectively, based on utilization data demonstrating the provision of primary care services to beneficiaries in prior periods. The second option is that beneficiary assignment could occur at the end of the performance year, or retrospectively, based on utilization data demonstrating the provision of primary care services to beneficiaries by ACO physicians during the performance year. However, as we discuss later in this final rule, these two basic approaches could be combined in any number of ways in an attempt to realize the most positive aspects of each approach and/or avoid the major disadvantages of each. For example, prospective assignment of beneficiaries could be combined with a retrospective reconciliation process that adjusts for certain prospectively assigned beneficiaries who have moved or changed health care providers during a performance year.

We proposed to adopt a retrospective approach for a number of reasons. First, the actual population served by a set of physicians changes significantly from year to year. Because Medicare FFS beneficiaries have the right to see any enrolled physician, there is typically more year-to-year variability in treating physicians for this population when compared to patients in managed care programs. Analysis of the PGP population did show approximately a 25 percent variation in assignment from year to year. If population seen by an ACO changes by 25 percent during the year, a prospectively assigned beneficiary population would reflect some beneficiaries who did not actually receive the plurality of their care from physicians in the ACO during the performance year. Final retrospective assignment of the population, on the other hand, would include in the actual performance year expenditures for an ACO only for those beneficiaries who received a plurality of their care from the ACO during the performance year.

Second, identifying an assigned beneficiary population prospectively may lead an ACO to focus only on providing care coordination and other ACO services to this limited population, ignoring other beneficiaries in their practices or hospitals. Given that the goal of the Shared Savings Program is to change the care experience for all beneficiaries, ACO participants and ACO providers/suppliers should have incentives to treat all patients equally, using standardized evidence-based care processes, to improve the quality and efficiency of all of the care they provide, and in the end they should see positive results in the retrospectively assigned population.

In the proposed rule, we acknowledged that there are merits in both approaches. It does seem appropriate for an ACO to have information regarding the population it will likely be responsible for in order to target its care improvements to those patients who would benefit the most. At the same time, we expressed our concern that we did not want to encourage ACOs to limit their care improvement activities to the subset of their patients that they believe may be

assigned to them. Finally, we considered that it was important that the assessment of ACO performance be based on patients who received the plurality of their primary care from the ACO in that performance year. Even under a more prospective assignment approach, there is reason to believe that a final retrospective redefinition of the assigned population to account for changes from prior periods would be required to ensure that the ACO is not held accountable for patients for whom it was not possible to provide care during the performance year. Under a more prospective system, the assignment would have to be adjusted every performance year to account for beneficiaries entering and leaving FFS Medicare and for those patients who move in and out of the geographic area of the ACO, as well as potentially other adjustments.

Considering the merits of both approaches, we took the position in the proposed rule that a retrospective approach to beneficiary assignment for purposes of determining eligibility for shared savings was preferable. We stated that the assignment process should accurately reflect the population that an ACO is actually caring for, in order to ensure that the evaluation of quality measures is fair and that the calculation of shared savings, if any, accurately reflects the ACO's success in improving the quality and efficiency of the care provided to the beneficiaries for which it was actually accountable. However, we also acknowledged the potential advantages of a more prospective approach, especially in providing ACOs with information about the patient population that is necessary for purposes of more effectively planning and coordinating care.

In the proposed rule, we also noted that in response to the November 17, 2010 RFI, of the few commenters favoring retrospective assignment, a group of commenters suggested the use of retrospective assignment for determining utilization and shared savings, but prospective assignment for purposes of determining which beneficiary identifiable data we would share with ACOs. We agreed that, given appropriate safeguards for maintaining the confidentiality of patient information, providing ACOs with meaningful information about their ''expected assigned population'' with the potential to identify an ''estimated benchmark target'' would be helpful. We discuss our policies regarding providing information to ACOs to help them understand their patient populations and better manage their care in section II.D. of this final rule.

Therefore, we proposed the combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of aggregate beneficiary level data for the historically assigned population of Medicare beneficiaries during the benchmark period. As we discussed in section II.D. of the proposed rule, we also proposed to provide ACOs with a list of beneficiary names, dates of birth, sex, and HCIN derived from the assignment algorithm used to generate the historical benchmark. We concluded that providing data on those beneficiaries that were assigned to an ACO in the benchmark period would be a good compromise that would allow ACOs to have information on the population they will likely be responsible for in order to target their care improvements to that population while still holding ACOs accountable only for the beneficiaries for whom they actually provided services during the performance year. We believed that such a combined approach would provide the best of both approaches while minimizing the disadvantages of either. We solicited comment on this approach.

Comment: The commenters were overwhelmingly in favor of prospective assignment. Many commenters, including MedPAC, argued that prospective assignment was important so that beneficiaries would have full knowledge of their inclusion in an ACO in advance and indeed that prospective assignment is necessary to engage beneficiaries effectively in the ACO process of more efficient and higher quality care. One commenter argued that retrospective assignment actually denies a beneficiary real choice, noting our observation in the proposed rule that under retrospective assignment it is not possible to inform beneficiaries of their assignment with an ACO in advance of the period in which they may seek services from the ACO. Most of these commenters also argued that prospective assignment is necessary to allow ACOs to plan care appropriately for the patients assigned to them. One commenter observed that a retrospective assignment method raises concerns about the ability of ACOs to manage population health in a way that generates savings. The commenter contended that providers need to know which patients for whom they are responsible in order to effectively coordinate care and implement care management program, and as a result, retrospective assignment could discourage participation in the Shared Savings Program.

Many commenters in favor of prospective assignment either denied that prospective assignment would lead to higher quality care for ACO patients than for others, or contended that the Shared Savings Program quality measures and monitoring activities would prevent and/or correct such behavior. One commenter argued that professional ethics and standards require that physicians not provide a lower level of care to one group of patients compared to another; the profession's commitment to its own ethics therefore will mitigate against ACO's providing a lower level of care to patients not prospectively attributed to it. Another commenter, however, acknowledged that an ACO would have a built-in incentive to discourage particularly high cost patients from joining their ACO since it would put the potential savings they might recoup at the end of the performance year in jeopardy, unless there is adequate risk adjustment.

A health care policy institute noted that 30 percent of beneficiaries attributed to an ACO in the current performance year were not attributed in the prior year. This suggests that basing attribution on data prior to the current performance year will lead to incorrect attribution of a substantial proportion of patients; using older years of data for attribution will lead to an even worse fit. Furthermore, 87.6 percent of patients seen by the ACO primary care physicians in a given performance year will be attributed to the ACO, so that the vast majority of patients utilizing services at an ACO will be attributed to the ACO. This commenter therefore recommended that we introduce a modified prospective methodology of attribution with current performance year data by adopting a near concurrent attribution model in which the ACO is held responsible only for the patients that received the plurality of their care from the ACO professionals within the ACO during a time period close enough to the performance year that it approximates the population seen during the year, and does not provide opportunities for gaming. Two commenters suggested alignment based on the prior 2 years weighted 50/50.

One commenter asserted that retrospective assignment undermines quality and cost objectives, and is unnecessary to avoid adverse selection. Noting that our stated goal is to prevent avoidance behavior around high-risk beneficiaries, this commenter recommended that an ACO applicant submit a panel of participating providers, including specialists, to CMS. We would use this list to look back at

the previous year's claims for primary care services provided by the primary care and/or specialty physician for the ACO beneficiaries. Patient assignment by CMS could be based on the plurality of primary care service visits provided. The ACO would then ensure that the individuals assigned by CMS were still the patients of the listed providers. One commenter argued that, by seeking to evaluate ACOs only on care actually rendered, we may be incentivizing ACOs to act directly contrary to the goal of having ACOs redesign care processes to improve care for all beneficiaries. Under the proposed rule, according to the commenter, ACOs will have every incentive not to redesign care processes so that high-risk, high-cost individuals are motivated to receive their care outside of the ACO.

Another commenter specifically questioned whether retrospective assignment would be appropriate for high risk populations and beneficiaries with special needs. Specifically, the commenter acknowledged that the methodology we proposed might be effective for the general Medicare population, but questioned how effective it would be for a high-risk population with complex medical problems and other special needs, stating that special needs beneficiaries would be better served by a more targeted approach that identifies a specific population, develops a model of care around the target risk group and predefines shared savings criteria in advance.

One commenter argued strongly for prospective assignment, but then stated: ''If CMS elects to use a retrospective patient assignment, then the Agency should consider providing the ACO with a list of 'potential' ACO patients prior to the beginning of the performance period.'' In a follow-up comment, however, this same commenter came down firmly in favor prospective assignment: ''We believe the final rule should include an option for an ACO to identify its population prospectively. With prospective assignment, ACOs can create systems to actively manage and engage patients * * * Restricting the beneficiary assignment to a retrospective methodology hampers ACOs' abilities to manage their patients proactively and effectively.''

A few commenters expressed conditional support for retrospective assignment. For example, one commenter stated that they understand the benefits and costs of both prospective and retrospective attribution. While recognizing the concerns that surround prospective attribution, including potential ''cherry-picking'' of patients, the commenter stated that patients have a legitimate interest in understanding which providers are in charge of their care and the incentives those providers have to provide quality care and reduce health care costs. Some of the commenters who argued for prospective assignment acknowledged that retrospective adjustments would be necessary to correct for changes such as beneficiaries that had moved out of the area, beneficiaries who had chosen to receive their services elsewhere, and for other similar matters. One commenter stated that the basic problem with ''pure'' prospective assignment (no reconciliation after the end of each performance year) in the Shared Savings Program is that it would: (1) Not give ACOs accountability for additional beneficiaries they take responsibility for during the performance year; and (2) give them accountability for beneficiaries they were no longer responsible for. A commenter also accepted retrospective assignment as manageable if the beneficiaries are assigned on a plurality of services provided, and if beneficiary data are shared prospectively during the benchmark period. Another commenter supported our hybrid approach to provide preliminary assignment information to ACOs combined with retrospective reconciliation, which will ensure ACOs are only assigned patients they provide care for during the performance year. Another commenter urged us ''at a minimum * * * to move further down the continuum toward some hybrid approach between prospective assignment and retrospective attribution.''

A few commenters recommended a hybrid approach combined with incentives for beneficiaries to enroll in an ACO, specifically, by modifying the patient assignment component of the rule to allow beneficiaries that prospectively enroll in an ACO to enjoy a portion of the savings that the ACO realizes, perhaps through a lower Part B premium.

A much smaller number of commenters agreed with our proposal for retrospective assignment. One commenter stated that retrospective assignment, though imperfect, is the only way to assign savings based on actual performance, and will encourage unbiased treatment. However, this same commenter requested an exception for primary care physicians who see high-risk patients for a single encounter. The commenter believed that omitting such patients from retrospective assignment for purposes of the shared savings payment calculations would avoid discouraging primary care physicians from taking on new, high-risk beneficiaries.

Another commenter was persuaded by the argument that retrospective assignment of beneficiaries to the ACO would create an environment where ACOs would be encouraged to provide effective care coordination for all beneficiaries with complex illnesses, but was nonetheless concerned that patient engagement would be more difficult when beneficiaries are not aware of the new delivery system. Another commenter strongly supported retrospective assignment as a more seamless approach, because prospective assignment would employ less reliable data, for example, data for patients who have moved or chosen a different provider. Another stated that early attribution may encourage providers to focus only on attributed beneficiaries and slow the implementation of wider scale changes.

A physician society believed the combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of beneficiary data and aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period is optimal, because it would provide ACO physicians with the information needed to manage their patient population, yet encourages high quality services to all beneficiaries. Another commenter was satisfied that the benefits of retrospective beneficiary assignment will likely outweigh any the concerns about choice that might remain because of the beneficiary notification, education and claims data-sharing opt-out provided for under the proposed rule. ''Retrospective assignment will likely encourage ACOs to provide the same level and type of services under consistent care delivery models to their entire beneficiary population.''

A patients' advocacy organization supported the agency's decision to assign beneficiaries retrospectively, out of fear that that prospective assignment might carry some risk that providers would ''cherry pick'' and seek to avoid certain high-risk individuals.

A physician society also supported our proposal: ''Because of [our] concerns with risk avoidance and other means to reduce costs and therefore create greater shared savings, we agree with the CMS decision to provide retrospective assignment. The proposal to provide prospective patient data to the ACO should provide the entity with the general patient population and other

demographic data that could help the ACO to make necessary decisions.''

A member of Congress also strongly supported our proposal for retrospective assignment: ''I support CMS' decision to assign Medicare beneficiaries retrospectively. I understand that many in the provider community would prefer prospective assignment, but fear it could create a two-tier system where assigned beneficiaries receive a heightened level of care and attention while the remainder of the patient population receives a lower level of care. Our intent in creating ACOs was to once again use Medicare to drive systematic, positive change in the delivery system. Retrospective assignment helps accomplish this goal by ensuring the best care for all.''

Another commenter believed that the method of assignment is less important than ensuring that ACOs receive information sufficient to understand and target their patient populations. Therefore, the commenter commended us for proposing to combine retrospective assignment with extensive data sharing about beneficiaries historically assigned and likely to be assigned to the ACO.

A few commenters suggested allowing ACOs a choice of prospective or retrospective assignment. One commenter would allow ACOs to elect either prospective or retrospective attribution of patients, adding that, if limited to one approach, prospective attribution is the only method compatible with population health management and its requirements.

Response: We appreciate the commenters' arguments about the advantages of a more prospective assignment methodology for purposes of patient care planning and other objectives. The intention of our proposal for retrospective assignment with prospective provision of beneficiary data was to strike an appropriate balance between the two approaches of prospective and retrospective assignment. In this final rule we similarly seek to strike an appropriate balance by accommodating the advantages of the prospective approach to a greater degree, moving, as one commenter suggested further down the continuum toward a more prospective approach, without abandoning our proposal to determine final assignment retrospectively.

We continue to believe that we should avoid as much as possible outcomes in which ACOs could be held accountable for costs related to beneficiaries who received care from ACO physicians in a prior year, but later moved away and received no services from the ACO during the performance year. We believe that ACOs should not be held accountable for the costs of patients for whom they are no longer to provide primary care due, for example, to a patient moving out of area during a performance year. Similarly, we believe that ACOs should have the opportunity to share in any savings realized through the application of the ACO's health planning, care coordination, and quality programs to patients who begin receiving primary care services from the ACO during a performance year. We took special note of the commenters who recommended prospective assignment with at least some retroactive adjustments to account for situations where prospective assignment would lead to negative or even unfair consequences for the ACO. We believe that the recommendations of these commenters amount to hybrid approaches that are not entirely dissimilar from our proposal, but that place a greater emphasis on the prospective elements of the hybrid than our proposal did. In light of the concerns raised by commenters, we agree that our proposal for a hybrid approach identifying a preliminary prospective population and then determining the final assignments at the end of the performance year should be modified in ways that further enhance its prospective aspects.

Therefore, in this final rule, we are modifying the policy that we proposed in response to comments to adopt a preliminary prospective assignment methodology with final retrospective reconciliation. Under this model, we will create a list of beneficiaries likely to receive care from the ACO based on primary care utilization during the most recent periods for which adequate data are available, and provide a copy of this list to the ACO. During the performance year, we will update this list periodically on a rolling basis to allow the ACO to adjust to likely changes in its assigned population. (We describe the nature and timing of this updating in the discussion of data sharing in section II.D. of this final rule.) At the end of each performance year, we will reconcile the list to reflect beneficiaries who actually meet the criteria for assignment to the ACO during the performance year. Determinations of shared savings or losses for the ACO will be based on this final, reconciled population. We believe this preliminary prospective assignment model with retrospective reconciliation will provide the ACO adequate information to redesign care processes while also encouraging ACOs to standardize care for all Medicare FFS beneficiaries instead of a subset. At the same time, we also believe that a preliminary prospective model with retrospective reconciliation will provide adequate incentives for each ACO to provide quality care to its entire beneficiary population.

It is important to note that the CMS Center for Medicare and Medicaid Innovation has announced a Pioneer ACO Model which will test alternative savings and alignment (the equivalent of assignment under the Shared Savings Program) () models as we proceed with implementing the Shared Savings Program. Under the Pioneer ACO Model, an ACO may select either prospective or retrospective alignment of beneficiaries. Under the prospective approach CMS will identify the population of Medicare beneficiaries for whom an ACO is accountable through analysis of the prior 3 years of fee-for-service claims data (weighted 60 percent for the most recent year, then 30 percent for the previous year, and 10 percent for the earliest year). The actual historical data for these beneficiaries will make up the benchmark spending. Pioneer ACOs that select prospective alignment will be accountable for the cost and quality outcomes of all their prospectively aligned beneficiaries at each end-of-period reconciliation, with certain exceptions. We will consider beneficiaries as no longer being in the ACO's designated patient population for purposes of performance measurement and expenditure calculations if they: (1) Have any months of Medicare Advantage enrollment or enrollment in only Part A or only Part B at any point during the performance period; (2) transfer their Medicare address to a Core Based Statistical Area (CBSA) or rural county that is not adjacent to that of the ACO's location (where the majority of its clinicians are located); or (3) receive more than 50 percent of their evaluation and management allowed charges in non-adjacent CBSAs or rural counties during the performance period. The adoption of this approach under the Pioneer ACO Model will provide us with an opportunity to gain experience and evaluate a more prospective hybrid model than the approach that we are adopting in this final rule. We will study the results of the Pioneer ACO Model very carefully, and will consider in our next rulemaking whether it is appropriate to revise our approach to assignment in the Shared Savings Program in the light of those interim results.

Comment: Many commenters, including MedPAC, argued that beneficiaries should be allowed to opt

out of assignment to an ACO (not just, as we proposed, of data sharing), even if they want to continue receiving services from ACO participants. A number of commenters went further to argue that beneficiary choice should be the sole basis for assignment to an ACO, that is, that beneficiary assignment to ACOs should actually be more like a process of beneficiary enrollment in an ACO. For example, one insurance organization recommended a ''physician-of-choice solution.'' A physician society recommended that CMS should prospectively allow patients to choose their own Medicare ACO. Other commenters referred to assignment based on the beneficiary's identification of their ''primary care provider or medical home.'' A national organization of physicians recommended that, instead of retrospective attribution, CMS should adopt a prospective approach that allows patients to volunteer to be part of the ACO and permits the ACOs to know up-front those beneficiaries for whom the ACO will be responsible.

Another commenter recommended that beneficiaries should opt in to the ACO (as the MA program is currently administered) rather than retrospective assignment. The commenter noted our statement in the proposed rule that the ''successful creation of this relationship is not possible when beneficiaries are not aware of the new delivery system available through ACOs and the possibility of being included in the population assigned to an ACO.''

Yet another commenter argued that, since Medicare beneficiaries must elect to participate in a MA organization, we should explain why we are not giving Medicare eneficiaries the option or the opportunity to elect to participate in the Shared Savings Program. The commenter believes that, by forcing Medicare beneficiaries into a shared savings program, the savings projected in the regulatory impact statement are unrealistic unless ACOs reduce care for their assigned Medicare beneficiaries.

These arguments were cast primarily in terms of giving beneficiaries the maximum opportunity for free choice about their participation in the Shared Savings Program. (Some of these commenters also contended that adopting this policy would allow us to abandon the proposal restricting primary care physicians to participation in one ACO, which we adopted to prevent uncertainty in the assignment process.)

Response: In the proposed rule, we emphasized that 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 practitioners from whom they receive their services. Rather, the statutory term ''assignment'' in this context refers only to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from a specific ACO so that the ACO may be appropriately designated as being accountable for that beneficiary's care. We also emphasized that the continued exercise of free choice by beneficiaries in selecting the physicians and other health care practitioners from whom they receive their services is a presupposition of the Shared Savings Program, in the sense that assignment would be based on each beneficiary's exercise of free choice in seeking primary care services.

We appreciate that those commenters advocating freedom for beneficiaries to opt out of assignment to an ACO, as well as those advocating that assignment actually be based on voluntary choice or enrollment by beneficiaries, are advancing these recommendations as means of extending the principles of beneficiary free choice that we enunciated in the proposed rule. However, we do not believe that ACO enrollment is an ''appropriate method to assign Medicare fee-for-service beneficiaries to an ACO'' as required by the statute because enrollment is a process that fits better in the context of MA, and the Shared Savings Program is certainly not intended to be a managed care program in a new guise. One important distinction between an ACO and many MA organizations is that beneficiaries are not locked into receiving services from the ACO to which they are assigned, and may continue to seek care from any provider they choose. Furthermore, the statute specifies that ''the methodology for assigning Medicare FFS beneficiaries to an ACO'' must be ''based on their utilization of primary care services provided under this title'' by physicians who are providers/suppliers in the ACO. A prospective approach that allows patients to volunteer to be part of the ACO would completely sever the connection between assignment and actual utilization of primary care services. A patient could volunteer to be part of an ACO from which he or she had received very few services or no services at all. An attempt could be made to mitigate this concern under a voluntary enrollment process for assignment by requiring that a beneficiary receive a minimum number or proportion of services from the ACO for the enrollment to be effective. But such measures would begin to transform a ''voluntary'' selection process into something more like the kind of statistical attribution model that we proposed and that most commenters endorsed (whether they preferred prospective or retrospective statistical attribution). Similarly, we do not believe it is necessary to provide an opportunity for a beneficiary to opt out of an ACO in order to preserve adequate beneficiary free choice. Beneficiaries remain free to seek services wherever they wish, and assignment results only from a beneficiary's exercise of that free choice by seeking and receiving services from ACO providers/suppliers. We understand the concerns of the commenters that beneficiaries may prefer leaving existing relationships with their provider in order to avoid being subject to the ACO's interventions. However, for the reasons we just stated, we do not believe that an enrollment mechanism or voluntary beneficiary ''opt-in'' would be appropriate.

Comment: Some other commenters argued for certain restrictions on beneficiary free choice. Some of these commenters argued that beneficiaries who opt out of data sharing should also be excluded from the ACO, on the grounds that it would not be fair to hold ACOs accountable for the care of patients unwilling to share the data necessary for planning efficient and high quality care. Another asserted that we had proposed ''the worst of both worlds for both the beneficiary and the providers,'' because beneficiaries can opt-out of data-sharing but not the program, which would prevent providers from having sufficient information to properly care for and manage the beneficiaries. The commenter argued that the best approach would be to allow beneficiaries the opportunity to fully withdraw from the program without having to seek care from another provider; structuring an opt-out option that prevents both data-sharing and attribution of that beneficiary to an ACO while allowing them to continue seeking care from their usual providers.

A commenter supported the patient's freedom to choose a provider and hoped that patients always have such a right. However, the commenter also argued that holding an ACO accountable for financial results of a patient who expressly chooses not to participate in critical elements of quality and care coordination is in conflict with the very purpose of an ACO. The commenter

therefore recommended that the experience and data for a beneficiary should be deleted for the entire year when the beneficiary chooses to ''opt out'' of the critical and core process of information sharing for quality improvement and care coordination, and would not be brought back in until the beneficiary has exercised an ''opt-in'' process or meets the criteria for assignment to a different ACO.

Other commenters argued that some restrictions on assigned beneficiaries seeking services outside the ACO may be necessary and appropriate in order for the ACO's measures to provide more cost-efficient care to be effective. One commenter suggested that unrestricted beneficiary choice poses a tremendous impediment to successful ACO operation, and that, while significant restrictions on beneficiary behavior may be undesirable, providing ACOs with the ability to more carefully direct and manage the care of high-cost patients would be a significant improvement to the Shared Savings Program.

Another commenter objected that ACOs may not discourage patients from seeking care outside an ACO, yet are financially liable for unmanageable patient behavior. The commenter recommended that ACOs should not be held responsible for unmanageable patient behavior unless the patients are restricted to using ACO-providers/suppliers, and that there should be some acceptable incentives to keep beneficiaries in the ACO, such as preferred provider rates.

Another commenter recommended adopting such restrictions along with establishing a ''gatekeeper'' model for ACOs, under which primary care physicians who are ACO providers/suppliers in an ACO would be in a position to identify the Medicare beneficiaries in the ACO and effectively coordinate care with efficient healthcare providers that are as equally focused (and incentivized) on both quality and cost. Without this control, the commenter believes that it would be difficult to hold the PCP accountable for the quality and cost of services received by the beneficiary.

Yet another commenter contended that ACOs need the ability to require or incentivize a patient to use ACO providers otherwise it will be nearly impossible to be held accountable for cost and quality of a population's health care. And another commenter argued that an ''any willing provider'' approach would prevent ACOs from developing specialty care focused networks and limiting network participation to providers that meet specific quality standards and other criteria that ACOs may wish to establish, thus compromising their' ability to meet cost and quality standards that qualify providers for shared savings.

On the other hand, some commenters urged us to confirm and/or emphasize certain basic beneficiary rights, such as the right ''to receive care outside the Medicare ACO at no penalty to the patient.'' A nursing organization recommended clear and explicit language to reassure beneficiaries about the process [of opting out] and its pros and cons, and that there is no limit, penalty, or modification to their services by choosing to opt out. Another commenter urged that we seek a mechanism to measure whether patients in an ACO are restricted by physician influence not to seek care outside the ACO and that patients are receiving necessary care in a timely manner, expressing the concern that primary care providers may try to manage a patient's condition and not appropriately refer the patient to a specialist because the potential higher cost of specialty care will potentially decrease the ACO's chances of meeting CMS benchmarks and achieving shared savings.

Another commenter strongly supported our decision to allow beneficiaries to seek care outside of the ACO if they desire. The commenter noted that this policy provides important reassurance to Medicare beneficiaries who can be wary of change and who may react negatively if they believe they are being ''locked in'' to a new system without their consent. Another commenter agreed that a beneficiary's freedom to choose providers is especially critical to Medicare beneficiaries who have multiple chronic conditions or other complex medical conditions. Furthermore, the commenter recommended that we should confirm that beneficiaries will also have the freedom to seek care for particularly complex medical conditions or treatments from experienced providers at recognized centers of excellence.

Response: We strongly believe that it would be inappropriate for the Shared Savings Program to incorporate features such as a beneficiary ''lock-in'' to providers within the ACO, automatic exclusion of certain types of beneficiaries, or similar measures advocated by some commenters. An essential element of what distinguishes the Shared Savings Program from a managed care program is precisely the absence of any ''lock-in'' restrictions and financial or other penalties for beneficiaries that seek services from the specialist physicians and other practitioners of their choice. Beneficiaries who are assigned to ACOs under the Shared Savings Program remain Medicare fee-for-service beneficiaries, retaining their full freedom of choice regarding where to receive services. We therefore take this opportunity, as requested by a number of commenters, to confirm and emphasize that basic beneficiary rights are maintained under the Shared Savings Program, most especially (but not exclusively) the right to receive care from physicians and other medical practitioners of their choice outside the ACO at no penalty to the patient.

Comment: A commenter recommended that ACOs should have the option of excluding from assignment certain patients, such as those patients expected, based on the most recent historical claims data, to get a very high percentage of their care from non-primary care physicians (the ''specialty-managed patient'' factor), and those permanently relocating away from the ACO's service area early in the contract period, for example before the six-month mark each year (the ''former patient'' factor).

Another commenter recommended a number of exclusions from assignment to ACOs, including Medicare beneficiaries older than age 75, Medicare beneficiaries living in a skilled nursing home or a nursing home, Medicare beneficiaries that receive Medicare based on end-stage renal disease, and Medicare beneficiaries who are diagnosed with AIDS, Alzheimer's, cancer, heart disease, or a similar diagnosis.

A commenter recommended that dialysis patients should be excluded from assignment to an ACO, on the grounds that there is a strong likelihood that ACOs will not want to assume the responsibility for patients on dialysis or at a high risk for initiating dialysis or receiving a kidney transplant. The commenter believes that this may have a negative effect on kidney patients' access to the most appropriate care, especially in regions with just one ACO, an ACO with the minimal number of beneficiaries, or with nominal provider diversity. The commenter thus urged that, to ensure patient access to, and the quality of, dialysis care and transplantation options are not compromised as a result of the ACO program, dialysis and transplant patients should not be included as ACO beneficiaries.

Response: We believe that adopting restrictions or exclusions on beneficiaries with certain conditions or utilization patterns from assignment to ACOs under the Shared Savings

Program would be inappropriate. The purpose of the Shared Savings Program is to promote accountability for a patient population and coordination of items and services under Parts A and B and to encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Because beneficiaries with serious conditions may receive the greatest benefits from greater accountability, enhanced coordination, and redesigned care processes, the goals of the program would be undercut if these beneficiaries were excluded from the program. The statute itself requires that we monitor ACOs to prevent avoidance of ''at risk'' beneficiaries. Specifically, section 1899(d)(3) of the Act provides that: ''[i]f the Secretary determines that an ACO has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO the Secretary may impose an appropriate sanction on the ACO, including termination from the program.'' The statute thus clearly assumes that beneficiaries with severe and chronic conditions that may increase costs will and should be included in beneficiary population assigned to an ACO. Otherwise, there would be no need to monitor whether ACOs have taken steps to avoid assignment of such beneficiaries to the ACO.

Comment: One commenter objected that Medicare beneficiaries do not get to pick their primary care physicians, but are assigned to them a year after they begin participating in the ACO based on who they used in the past. The commenter therefore asked: ''How is Medicare going to determine how to assign the beneficiaries without overloading one doctor more than others?''

Response: Beneficiaries are assigned to ACOs on the basis of services they actually receive from physicians in an ACO during a performance year. Assignment thus presupposes beneficiary choice of the specific physician or physicians from whom they receive services. Beneficiaries are assigned to ACOs for the purposes of holding the ACO accountable for the quality and cost of care provided to the beneficiary. However, beneficiaries are not assigned to a particular physician, and remain free to seek care from any physicians they choose. Similarly, physicians are not required to accept patients beyond the limits on patient loads that they establish for their practices. Therefore, the operation of the Shared Savings Program in no way threatens to overload some doctors more than others.

Comment: One commenter recommended against exclusive attribution of beneficiaries to only one ACO, on the grounds that it is likely that more than one ACO will provide services to a beneficiary during a performance year. The commenter recommended shared attribution with savings shared in proportion to the total billed services of each ACO.

Response: Section 1899(c) of the statute refers to the assignment of ''Medicare fee-for-service beneficiaries to *an* ACO.'' (Emphasis supplied.) Therefore it is not clear the statute would permit shared assignment and shared attribution of savings to more than one ACO. We also note that adopting this policy would create a degree of operational complexity for both the Medicare program and for participating ACOs that we do not believe to be acceptable, especially in the early stages of the program.

Final Decision: Under § 425.400 of this final regulation, we are revising our proposed policy to provide for prospective assignment of beneficiaries to ACOs in a preliminary manner at the beginning of a performance year based on most recent data available. Assignment will be updated quarterly based on the most recent 12 months of data. Final assignment is determined after the end of each performance year based on data from that year. We are also finalizing our proposal that beneficiary assignment to an ACO is for purposes of determining the population of Medicare FFS beneficiaries for whose care the ACO is accountable, and for determining whether an ACO has achieved savings, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services. Beneficiaries assigned to ACOs under the Shared Savings Program retain their full rights as Medicare fee-for-service beneficiaries to seek and receive services from the physicians and other medical practitioners of their choice. No exclusions or restrictions based on health conditions or similar factors will be applied in the assignment of Medicare FFS beneficiaries. We are also finalizing our proposal to determine assignment to an ACO under the Shared Savings Program based on a statistical determination of a beneficiary's utilization of primary care services, rather than on a process of enrollment or ''voluntary selection'' by beneficiaries. The specific methodology (the ''step-wise'' approach) is described in § 425.402. In that methodology, we are also finalizing our proposal to assign beneficiaries to no more than one ACO.

3. Majority vs. Plurality Rule for Beneficiary Assignment

Section 1899(c) of the Act requires that Medicare FFS beneficiaries be assigned to ''an ACO based on their utilization of primary care services'' furnished by an ACO professional who is a physician, but it does not prescribe the methodology for such assignment, nor criteria on the level of primary care services utilization that should serve as the basis for such assignment. Rather, the statute requires the Secretary to ''determine an appropriate method to assign Medicare FFS beneficiaries to an ACO'' on the basis of their primary care utilization.

An obvious general approach would be to make such an assignment on the basis of some percentage level of the primary care services a beneficiary receives from an ACO physician. In the proposed rule, we considered the more specific issue of whether to assign beneficiaries to an ACO when they receive a plurality of their primary care services from that ACO, or to adopt a stricter standard under which a beneficiary will be assigned to an ACO only when he or she receives a majority of their primary care services from an ACO.

Under the PGP demonstration beneficiaries were assigned to a practice based on the plurality rule. By employing a plurality standard for primary care services, our analysis indicates that between 78 and 88 percent of the patients seen for primary care services at the PGP during the year were subsequently assigned to that PGP group. As measured by allowed charges (evaluation and management CPT codes), the PGP provided on average 95 percent of all primary care services provided to the assigned patients.

We proposed to assign beneficiaries for purposes of the Shared Savings Program to an ACO if they receive a plurality of their primary care services from primary care physicians within that ACO. We believed that the plurality rule would provide a sufficient standard for assignment because it would ensure that beneficiaries will be assigned to an ACO when they receive more primary care from that ACO than from any other provider. This would result in a greater number of beneficiaries assigned to ACOs, which could enhance the viability of the Shared Savings Program, especially in its initial years of operation.

Comment: Some commenters addressed the specific issue of employing a plurality versus majority standard as the basis for beneficiary assignment. One individual maintained

(without elaboration) that deciding upon assignment of patients to ACOs on the basis of plurality rather than majority provider provision of services enhances the likelihood of financial penalties upon ACOs. A number of commenters recommended majority assignment in place of a plurality standard. One of these commenters contended that a plurality could lead to the undesirable consequence of accountability without responsibility whenever the percentage is less than the majority. The commenter noted that, by definition, a plurality is simply more than any other, and the proposed rule did not recommend any minimum percentage. Another commenter criticized our attribution proposal on the grounds that it would produce many patients who have very loose, if any, true connection to [an] ACO and its providers. The commenter recommended a majority standard as one of several measures to provide a stricter attribution standard that would only assign patients with relatively strong relationships to an ACO. Yet another commenter would revise and simplify the basis for assignment to be beneficiaries' receipt of a majority of their primary care visits, stating that the experience in local markets is that buy-in is greatest when providers are assured their population reflects the patients for whom they provide the most care and thus have maximum ability to affect through quality/efficiency improvements. This, according to the commenter, also helps to ensure the payment model will accurately reward (or penalize) their success (or deficiencies) in caring for their assigned population.

Some commenters expressed support for the plurality standard. One noted that using a plurality standard takes into account the variability in utilizing primary care physicians. Other commenters stated that a plurality standard was at least ''workable'' or ''acceptable.'' However, some of the commenters who expressed support for a plurality standard also endorsed adopting a minimum threshold for assignment

Response: We are finalizing our proposal to adopt a plurality rule as the basis for assignment. Adoption of a majority standard for assignment would necessarily result in the assignment of fewer beneficiaries to each ACO. Adopting a stricter majority standard would not be conducive to assignment of enough beneficiaries to ACOs for the Shared Savings Program to be viable or to make a contribution to improving quality and promoting more cost-effective care for Medicare beneficiaries. We also believe it is in the best interest of the participating ACOs to have more beneficiaries assigned to promote statistical stability. Moreover, we believe that use of a plurality standard creates a greater incentive for ACOs to redesign care processes for all FFS beneficiaries that receive care from the ACO and promotes accountability for patients that might otherwise fall through the cracks because they would not meet a majority standard. Finally, it is reasonable for an entity that provides more of a beneficiary's primary care than any other provider, to coordinate care for that beneficiary.

Comment: Several commenters were concerned about assignment of beneficiaries that received care outside of a reasonable geographic distance from the ACO. For example, a number of commenters expressed concern about the impact of ''snowbirds,'' beneficiaries who spend parts of each year in different locations, under the plurality standard for assignment. One noted that assigning patients to an ACO based on the plurality of primary care services provided will result in ACOs being responsible for patients who spend a significant portion of the year residing outside of the ACO service area, and that there is already great difficulty in trying to coordinate care for patients who split their residence between two locations. A number of these commenters cited the exclusion of ''snowbirds'' from MA plans as a precedent.

Another commenter also advocated a list of exclusions from assignment, including a geographic exclusion, noting that, by limiting the distance that the beneficiary may reside from the ACO participants, ACOs are more likely to be assigned beneficiaries who are able to seek other types of care from the ACO.

Similarly, a health care provider recommended that we should exclude beneficiaries who receive more than 50 percent of their evaluation and management allowed charges in non-adjacent communities during the performance year.

Response: With regard to the issues concerning ''snowbirds,'' beneficiaries who travel frequently, and similar situations, we believe that such situations pose a much smaller problem in the Shared Savings Program than they do in other programs, such as the MA program. This is because the assignment methodology under the Shared Savings Program is essentially self-correcting for the effects of seasonal migrations and extensive travel, since it directly reflects where a beneficiary receives the plurality of his or her primary care services. A beneficiary who travels or resides in more than one location will not be assigned to an ACO unless he or she receives the plurality of primary care from that ACO.

Furthermore, one reason for the exclusion of ''snowbirds'' from MA plans is that beneficiaries who make seasonal migrations cannot adhere to the network arrangements that are an intrinsic feature of managed care. The ACO model does not include the use of networks or any restrictions on where beneficiaries can receive care. It is true that ''snowbirds'' may be assigned to an ACO on the basis of receiving a plurality of primary care in one location, and that ACO will still be responsible for costs related to care in the alternate location. However, any beneficiary assigned to an ACO remains free to receive substantial amounts of care outside the ACO, even if they remain year-round within the geographical area of the ACO, and for reasons we have already discussed, we do not believe that it is appropriate to adopt restrictions and exclusions that hinder beneficiary freedom to choose where to receive care. We believe that this principle applies equally to the issue of seasonal migration (''snowbirds'') and other issues of geography (for example, distance from an ACO) that commenters raised. Therefore, we do not believe that it is appropriate to adopt restrictions or exclusions on assignment to account for seasonal migration or any other geographical factor in the Shared Savings Program

Comment: A CAH requested a very different assignment methodology, specifically, that all the beneficiaries in their service area be assigned to their rural ACO. The commenter explained that, if we were not to allow this model, rural patients would be unable to be properly assigned to an ACO, and the CAH would have to join other rural providers to meet the 5,000 beneficiary requirement.

Response: We believe that this suggestion is incompatible with the statute, which requires that assignment be based on the utilization of primary care services from a physician who is a provider/supplier in an ACO, not the location of beneficiaries within the area served by an ACO.

Comment: A number of commenters recommended establishing a minimum threshold of primary care services for assignment to prevent providers from being evaluated on beneficiaries for whom they provide limited services and thus have limited opportunities to influence care or coordination. Other commenters supported a two-visit threshold as the minimum for

beneficiary assignment. Several major medical institutions recommended that we establish a threshold of at least three visits which would provide more assurance of continuity with the ACO and more patients who have continuing needs. A medical association urged that there must be a floor to the plurality of primary care charges used for that assignment, recommending a floor of 20 percent—meaning that unless the ACO is responsible for at least 20 percent of a patient's primary care charges, that patient would not be assigned to any ACO. Another commenter recommended 25 percent. Yet another commenter advocated a minimum percentage between thirty and forty. And still another recommended 50 percent of primary care visits.

MedPAC discussed the possibility of establishing a 10 percent threshold (citing the Pioneer ACO demonstration threshold of 10 percent or less of E&M charges) in the course of endorsing the step-wise method of assigning beneficiaries: ''we would prefer the step-wise option which assigns beneficiaries first to primary care physicians if possible and then to certain specialty physicians if the share of evaluation and management visits (or charges) to primary care physicians falls below a threshold value. (The Pioneer ACO demonstration sets the threshold as 10 percent or less of E&M charges.)''

Response: In this final rule, we have decided not to adopt a threshold for assignment for reasons similar to those which motivated our decision to maintain a plurality standard for assignment. Adoption of a threshold, like adoption of a majority standard for assignment, would necessarily result in the assignment of fewer beneficiaries to ACOs generally and to each ACO in particular. We believe it is in the general interest of the Shared Savings Program, and in the best interest of each ACO, to have more beneficiaries assigned to promote statistical stability. Moreover, we believe that use of a plurality standard without a threshold creates a greater incentive for ACOs to redesign care processes for all FFS beneficiaries that receive care from the ACO, and thus promotes accountability for patients that may fall through the cracks because they fail to meet a minimum threshold.

Finally, in the proposed rule we considered the issue of how to determine when a beneficiary has received a plurality of primary care services from an ACO. We noted the plurality could be determined either on the basis of a simple service count or on the basis of the accumulated allowed charges for the services delivered. The method of using a plurality of allowed charges for primary care services would provide a greater weight to more complex primary care services in the assignment methodology, while a simple service count method would weigh all primary care encounters equally in determining assignment. We have previous experience with the method of using a plurality of allowed charges in the PGP demonstration. One advantage of this method is that it would have less need for tie-breaker rules, since it is unlikely that allowed charges by two different entities would be equal. On the other hand, this method does not necessarily assign the beneficiary to the entity that saw the patient most frequently, but rather to the entity that provided the highest complexity and intensity of primary care services.

We proposed to implement the method of using a plurality of allowed charges for primary care services to assign beneficiaries to ACOs. Allowed charges are a reasonable proxy for the resource use of the underlying primary care services, so the method of using a plurality of allowed charges assigns beneficiaries to ACOs according to the intensity of their primary care interactions, not merely the frequency of such services.

Comment: One commenter expressed concern that the method for determining from which primary care provider a patient received the ''plurality of care'' is problematic because it is measured by the ''sum of allowed charges.'' The commenter argued that this will tend to reward providers who may be paid more for the same service and providers who tend to provide higher priced procedures, and that while this does give the provider who generated the most costs the responsibility for containing costs, it may skew things if, for example, a patient gets one high cost procedure from one provider and the majority of their primary care somewhere else. The single procedure provider would generally be less able to improve care coordination and manage costs with respect to that patient than the ''regular'' provider.

Another commenter suggested that we modify the methodology for beneficiary assignment from plurality of allowed charges to number of encounters by a provider. ''If one of the goals of the Shared Savings Program is to achieve a healthier population, the greater the number of encounters, regardless of the allowed charges or the physician's specialty, provides increased opportunities to educate and impact the patient and influence his/her behavior.'' Another commenter also advocated using a visit-based standard to assessing majority, instead of the proposed allowed-charges approach. This commenter emphasized that the charges standard would skew patient attribution based on the illness severity of the patients. Another commenter cited the frequency of upcoding as a basis for using visit counts rather than charges.

Another commenter objected that we seem to believe that charges are reasonable proxy for the resource use of the underlying primary care service. The commenter argued that the potential downside of using charges is that it may entrench the overutilization or up-coding that we otherwise wish to avoid. The commenter thus suggested that ''a more balanced approach'' could be the use of the plurality of visits combined with an adjustment factor to reflect intensity.

A nursing association recommended, in conjunction with its proposal to count the services of NPs in the assignment process, an alternative to employing allowed charges as the basis for assignment. The commenter noted that, if non physicians such as NPs and PAs were to be included in the assignment process, they would be at a disadvantage if allowed charges are the basis for assignment. They explained: ''The problem here lies in the mandatory discount applied to approved charges from NPs and CNSs. Their approved charges for primary care services are set at 85 percent of the Medicare Physician Fee Schedule amount. This discounting of APRN primary care services can tip the balance as to whether the beneficiary is assigned to an ACO where he or she may have received primary care services from the ACO's primary care physicians but in lesser amounts than provided by the advanced practice registered nurse. Our preferred remedy in this case would be to follow the recommendations of the Chair of the IOM Study on the Future of Nursing and pay according to the value of the service rather than the specialty of the provider. Failing that, ACO assignment should be based on the plurality of the work RVUs associated with primary care services.''

Response: We considered most of the alternatives to the use of allowed charges in developing our proposal. We agree that the method of using a plurality of allowed charges would provide a greater weight to more complex primary care services in the assignment methodology, while a simple service method count would weigh all primary care encounters equally in determining assignment. However, we do not believe that a method of using allowed charges is

inappropriate. Although this method does not necessarily assign the beneficiary to the entity that saw the patient most frequently, the beneficiary will be assigned to the entity that provided the highest complexity and intensity of primary care services. This method also results in the assignment of the responsibility for containing costs to the provider who generates the most costs. Our previous experience with the PGP demonstration demonstrated an advantage of this method is that it does not require tie-breaker rules, since it is unlikely that allowed charges by two different entities would be equal. Assignment of beneficiaries on the basis of plurality in a simple service method count would require tie-breaker rules for those rare occasions when two or more entities delivered an equal number of services to a beneficiary.

We considered the nursing association's recommendation that we use RVUs rather than charges. Use of RVUs in place of allowed charges would retain many of the benefits of employing charges (for example, reduced need for a tie-breaker) while correcting for the effects of some factors in allowed charges that arguably should not affect assignment (for example, the application of GPCI values to the physician fee schedule payments). However, it is unclear whether it would be possible and how to include FQHC/RHC services in the assignment process if we were to base assignment on RVUs for specific HCPCS codes rather than allowed charges since, as discussed previously, we have not required that RHCs include HCPCS codes on their claims, and FQHCs have been required to report HCPCS codes only since January 1, 2012. Moreover, the use of allowed charges has resulted in satisfactory assignment results under the PGP demonstration. Therefore, we will retain this proven method of using allowed charges. We note that for purposes of the Shared Savings Program, allowed charges for FQHC/RHC services will be based on the interim payments, since any subsequent adjustments following settlement of their cost reports would not be available in time for assignment purposes. We will continue to consider the alternative of using RVUs as we gain experience under the Shared Savings Program.

Comment: Several commenters expressed concern about potential unintended consequences of the plurality rule, specifically consequences related to care coordination and manipulation of Medicare beneficiary attribution, particularly for beneficiaries who require SNF or NF care during the attribution time period. These commenters noted that similar concerns were raised in the Medicare Advanced Primary Care Practice Demonstration. As a result, they recommend that CMS monitor the plurality rule to ensure that it does not adversely impact patient care coordination or encourage ACO gaming of Medicare beneficiary attribution in the SNF or NF setting.

Response: We appreciate the commenters' recommendation, and we will certainly monitor the impact of the plurality rule to ensure that it does not adversely impact patient care coordination or encourage ACO gaming in any way. We discuss our monitoring plans in detail in section II.H. of this final rule.

Comment: One commenter had a technical comment about the plurality formula in the regulations text: ''Section 425.6(b) of the regulations provides the technical details of the assignment methodology in five steps. We have the following comments on the technical description: Step (3) calculates a single number—the total allowed charge for primary care services—for each beneficiary. The rule should clarify whether the intention for the plurality test is to calculate total allowed charges for each non-ACO provider or in aggregate for all non-ACO providers. Step (5) includes a plurality test but only references Step (4), which does not include non-ACO providers. Based on the rule, it appears that non-ACO providers are intended to be considered in the plurality test. Step (5), therefore, also should reference the total allowed charges for non-ACO providers in the plurality test.''

Another commenter noted that we proposed to assign beneficiaries to an ACO if they receive a plurality of their primary care services from primary care physicians within an ACO. In this formula, primary care services provided by specialists would be included in the total primary care services for the beneficiary, but would not be included in the count of the primary care services the beneficiary receives from an ACO. The commenter recommended that we should compare the primary care services beneficiaries receive from an ACO's primary care physicians only to the total primary care services beneficiaries receive from primary care providers, thereby excluding primary care services provided by specialists from the denominator in the plurality calculation.

Response: We agree with the first commenter that the regulations text needs to be revised to reflect the intention for the plurality test to calculate total allowed charges for each non-ACO provider for purposes of determining where the beneficiary received the plurality of his or her primary care services. In addition, we believe that our decision to include specialists in the assignment methodology by way of a step-wise process addresses the commenters' questions regarding whether primary care services furnished by specialists should be included in the computation of the plurality of allowed charges for primary care services.

Final Decision: In § 425.402, we are finalizing our proposal to adopt a plurality of primary care services, defined in terms of allowed charges, as the basis for assignment. However, we are modifying the way in which we will calculate that plurality in order to apply it in the two-step assignment process, as described previously.

F. Quality and Other Reporting Requirements

1. Introduction

In this section of the final rule, we discuss: Measures to assess the quality of care furnished by an ACO; requirements for data submission by ACOs; quality performance standards; the incorporation of reporting requirements under section 1848 of the Act for the Physician Quality Reporting System; and aligning ACO quality measures with other laws and regulations.

2. Measures To Assess the Quality of Care Furnished by an ACO

a. General

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization (such as rates of hospital admission for ambulatory sensitive conditions). Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. In the proposed rule, we indicated that we believe that the Secretary's authority to determine the form and manner of data submission allows for establishing requirements for submission of data on measures the Secretary determines to be appropriate for evaluating the quality of care furnished by the ACO, without regard to whether the Secretary has established a specific quality performance standard with respect to

those measures that must be met in order to be eligible for shared savings.

We proposed that an ACO be considered to have met the quality performance standard if it has reported quality measures and met the applicable performance criteria in accordance with the requirements detailed in rulemaking for each of the 3 performance years. We further proposed to define the quality performance standard at the reporting level for the first year of the Shared Savings Program and to define it based on measure scores in subsequent program years. We proposed the use of 65 measures to establish quality performance standards that ACOs must meet in order to be eligible for shared savings for the first performance period (76 FR 19571). We stated that quality measures for the remaining 2 years of the 3-year agreement would be proposed in future rulemaking.

Comment: While some commenters supported the 65 measures proposed without modification, the majority recommended that we adopt fewer, validated measures aligned with the three-part aim and currently in use in order to encourage participation, reduce reporting burden, and achieve more focused and meaningful improvements, particularly in the first agreement period. Commenters suggested paring down the number of quality measures in a number of ways, such as by using a more simplified framework and limiting measures to: A specific number; those that can be reported via a specific methodology such as claims; those currently reported through another program; only some of the proposed domains; outcomes measures; those related to the most prevalent and costly health conditions; or eliminating the measures that involve beneficiary compliance. Another commenter recommended having a ''performance set'' of measures that includes outcome-oriented, claims-based measures focused on utilization to determine eligibility for payment, and a ''reporting set of measures'' used for monitoring purposes only. A few commenters supported the number of measures proposed but were concerned about reporting burden. Another commenter noted that the proposed measure set may not be feasible initially but should be in the future, as it is in other sectors.

Response: We considered the commenters' recommendations carefully when determining the 33 final, required quality measures, which will be scored as 23 measures as discussed in section II.F.4. of this final rule. We are sensitive to the concerns raised by commenters regarding the administrative burden of the proposed measures, and we have modified our proposal by reducing the number of required measures by removing measures perceived as redundant, operationally complex, or burdensome and retaining those that would still demand a high standard of ACO quality, focus on priority areas and are areas of high prevalence and high cost in the Medicare population. We have also sought to finalize proposed measures or variations of proposed measures that align with the measures used in other quality programs and initiatives. We have also made certain adjustments to our proposed measures to align with updates in the measures, such as the retirement of certain measures. Further detail on the reasoning behind finalizing or removing specific measures is discussed in section II.F.2.c of this final rule.

Comment: Several commenters expressed concern about unintended negative consequences related to the quality measures and patients' role in improving quality of care outcomes. A number of commenters were concerned that ACOs might skimp or delay in providing specialty care, particularly high cost services or those not available within the ACO. Several commenters suggested a wider choice of measures for major illnesses in order to avoid underutilization. Another commenter was concerned that providers would treat patients based on the measures rather than on patients' needs. Several commenters were concerned that measures would track how many services are provided rather than how well care is provided.

One commenter suggested CMS consider patients' responsibility, and another commenter noted the proposed measures make providers accountable for patient decisions. One commenter suggested CMS add measures or program requirements that encourage ACOs to promote patient accountability for health and wellness. A few commenters suggested the proposed measures were not those that would have the greatest impact on quality or address the urgent need to evaluate the efficient use of healthcare resources. One commenter recommended that measures focus on misuse and overuse as much as underuse and suggested targeting the areas for misuse identified by the National Priorities Partnership.

Response: In addition to measuring quality for performance purposes, we also intend to monitor the quality of care furnished by ACOs in an effort to identify patterns of avoiding at-risk beneficiaries and misuse, underuse, and overuse of services over time. We will use data that we can calculate internally without requiring additional ACO reporting, such as claims and administrative data, to conduct this monitoring. Further information about program monitoring is addressed in section II.H of this final rule.

b. Considerations in Selecting Measures

We view value-based purchasing as an important step towards revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of volume. The Shared Savings Program is a critical element of our Medicare value-based purchasing initiative, in which we have sought to meet certain common goals, as described in the proposed rule (76 FR 19569).

Comment: Numerous commenters endorsed focusing measures around the three-part aim of better care, better health, and lower costs; some suggested that the proposed measures could go further in this regard. One commenter stated that the quality measures sufficiently address the care and improving health aims but do not address the reducing costs aim. Another commenter stated the proposed measures will add cost to providers and will not produce savings. Commenters also supported using tested, evidence-based and endorsed measures, and a number of commenters suggested that measures should: Be meaningful, improve patient outcomes, rely on clinically enriched administrative measures already in use and be consistent with measures used in other public programs, such as the PQRS, Electronic Health Record (EHR) Incentive Program, Medicare Advantage (MA), Hospital Value-Based Purchasing (HVBP), the Inpatient Prospective Payment System (IPPS), and others. Commenters also suggested a number of different measurement sets. One commenter was concerned that quality of care for individuals and populations are not genuine top priorities of the Shared Savings Program, since the proposed rule included only quality measures that cover the same patient populations, processes, and outcomes that are already addressed by existing measures used in other programs. A few commenters proposed only using PQRS measures initially. Many commenters suggested using only NQF-endorsed measures, while others asked that CMS not limit itself to NQF-measures.

Response: We agree that the quality measures should be tested, evidence-based, target conditions of high cost and high prevalence in the Medicare population, reflect priorities of the National Quality Strategy, address the

continuum of care to reflect the accountability that ACOs accept for their patient populations, and align with existing quality programs and value-based purchasing initiatives. At this time, we have concluded that it is most appropriate to focus on quality measures that directly assess the overall quality of care furnished to beneficiaries. We are adopting a measurement set that includes patient experience, outcomes, and evidence-based care processes. That said, we do not agree that specific measures addressing high cost services or utilization are necessary to incentivize ACOs to address these issues. We believe that the goal of lower cost growth will be achieved through improved coordination and quality and that the potential for shared savings will offer a sufficient incentive for ACOs to address utilization issues in a way that is most appropriate to their organization, patient population, and local healthcare environment. However, we may consider such measures in the future. Accordingly, the measures we are finalizing include a subset of the proposed measures that address the populations, processes, and outcomes that were the focus in the proposed rule.

In the proposed rule, we stated that our principal goal in selecting quality measures for ACOs was to identify measures of success in the delivery of high-quality health care at the individual and population levels. We considered a broad array of process and outcome measures and accounted for a variety of factors, prioritizing certain measures according to principles described in the proposed rule. (76 FR 19569) We believe endorsed measures have been tested, validated, and clinically accepted and have therefore selected the final measures with a preference for NQF-endorsed measures. However, the Act does not limit the Shared Savings Program to endorsed measures. As a result we have also exercised our discretion to include certain measures that we believe to be high impact but that are not currently endorsed.

c. Quality Measures for Use in Establishing Quality Performance Standards That ACOs Must Meet for Shared Savings

Based upon the principles described previously, we proposed 65 measures (76 FR 19571) for use in the calculation of the ACO Quality Performance Standard. We proposed that ACOs would submit data on these measures using the process described in the proposed rule and meet defined quality performance thresholds. We proposed that ACOs would be required to report quality measures and meet applicable performance criteria, as defined in rulemaking, for all years within the agreement period to be considered as having met the quality performance standard. Specifically, for the first year of the program, we proposed for the quality performance standard to be at the level of full and accurate measures reporting; for subsequent years, we proposed the quality performance standard would be based on a measures scale with a minimum attainment level. We proposed that ACOs that do not meet the quality performance thresholds for all measures would not be eligible for shared savings, regardless of how much per capita costs were reduced, which is discussed further in section II.F.4.b.2. of this final rule.

Comment: One commenter requested clarification on whether care provided outside the ACO would count toward the ACO's quality metrics. One commenter recommended we require measures reporting for all patients seen by the ACO, not just those assigned in order to simplify the reporting process and spur improvement across the ACO's entire patient population.

Response: Since ACOs will be accountable for all care received by their assigned beneficiary population, quality measures will reflect the care assigned beneficiaries receive from ACO providers and non-ACO providers. We will utilize claims data submitted by the ACO providers/suppliers as well as from providers outside the ACO in determining measure numerators and denominators.

Comment: A few commenters asked CMS to clarify whether the reporting performance standard would be applicable to ACOs only during the first year of the Medicare Shared Savings Program (that is, 2012) or for the first year of the ACO's agreement period and how this would affect a mid-year start date, if CMS decides to incorporate one. One of these commenters supported defining the quality performance standard at the reporting level for the first year of an ACO agreement period, regardless of whether this timeframe coincides with the calendar year.

Response: In this final rule, we have finalized first year start dates for ACO participants in April and July of 2012, but not for January 2012, as discussed in section II.C.1. of this final rule. We have also outlined a performance standard for each 12-month, calendar year quality measure reporting period. We indicated that ACOs requesting an interim payment calculation as described in section II.G.2.k of this final rule must completely and accurately report the ACO GPRO measures for 2012. We indicated that the final performance year 1 reconciliation for the first agreement period would be based on completely and accurately reporting all ACO quality measures—ACO GPRO, CAHPS and claims- and administrative-based measures—for CY 2013. Recognizing that ACOs' first performance year will be 18 to 21 months and carry from 2012 into 2013 if they start in the Shared Savings Program in April or July 2012, ACOs will need to comply with annual measures specifications updates detailed in subregulatory guidance. While we anticipate a relatively static set of quality measures for the first agreement period, ACOs will also be required to comply with any measures updates made in future rulemaking as clinical guidelines change and as other programs update their measure requirements. For instance, the EHR Incentive Program will release clinical quality measure requirements for Stage 2 Meaningful Use, and we believe it is advantageous and more efficient for the provider community if we can align measures across programs. It may also be necessary to add or remove measures from the Shared Savings Program as CMS gains experience with ACOs and develops a better understanding of the types of measures that are most important to assess the quality of care furnished by this new type of entity. Quality measures requirements for each performance year are discussed in Tables 1 and 2 as well as in section II.F.4 of this final rule.

ACOs that enter into an agreement period beginning in 2013 or subsequent years will be subject to the same rules unless they are revised in future rulemaking cycles. That is, absent some change to our policies, the quality performance standard for an ACO's first performance year will be set at the level of complete and accurate measures reporting. We expect that the measures we are finalizing will be maintained in the early years of the program as both ACOs and CMS develop infrastructure and gain experience with the program. We believe having one quality performance standard and set of measures for all ACOs will make for better longitudinal comparisons and be operationally more feasible and less burdensome.

In the proposed quality measures table (76 FR 19571), we categorized each of the measures into the goals of better care for individuals and better health for populations and included: The domain each of the proposed measures addresses, the measure title, a brief description of the data the measure

captures, applicable PQRS or EHR Incentive Program information, the measure steward or, if applicable, NQF measure number, the proposed method of data submission for each measure, and information on whether the quality performance standard for each measure is defined at the reporting or performance level for each year of the agreement period. We noted that while many of the proposed measures have NQF endorsement or are currently used in other CMS quality programs, the specifications for some of the proposed measures would need to be refined in order to be applicable to an ACO population. However, we proposed to align the quality measures specifications for the Shared Savings Program with the measures specifications used in our existing quality programs to the extent possible and appropriate for purposes of the Shared Savings Program. We also stated that we planned to make the specifications for the proposed measures available on our Web site prior to the start of the Shared Savings Program. We also acknowledged that we would expect to refine and expand the ACO quality measures in the future and expand measures reporting mechanisms to include those that are directly EHR-based. Specifically, we expect to expand the measures to include other highly prevalent conditions and areas of interest, such as frailty, mental health, substance abuse, including alcohol screening, as well as measures of caregiver experience. Finally, we also sought comment on a process for retiring or adjusting the weights of domains, modules, or measures over time.

We received the following comments about the proposed measures in general.

Comment: Many commenters expressed concern that few proposed measures were focused on outcomes as opposed to processes. One commenter who supported outcome measures wrote that a 3-year agreement period was too short to allow accurate outcomes assessment across diagnoses and expressed concern that the expectation that outcomes could be altered in this time frame might encourage gamesmanship and manipulation of data by ACOs.

Response: In selecting the final set of measures, we have sought to include both process and outcome measures, including patient experience of care. Process measures are typically easier to calculate based on administrative data, such as claims, and would require less reporting effort by ACOs, while outcomes measures would provide a more complete picture of quality of care improvement but would require more ACO reporting effort, such as GPRO measures that tend to rely on a combination of both claims and clinical quality data. Since ACOs are charged with improving and coordinating care and delivering high quality care but also need time to form and ramp up, we believe it is important to start with a combination of both process and outcomes measures, but may move to more outcomes-based measures and fewer process measures over time. We have modified our proposed domain structure in this final rule by combining the care coordination and patient safety domains to better align with other CMS value-based purchasing initiatives and the National Quality Strategy and to emphasize the importance of ambulatory patient safety and care coordination. In addition, we are moving certain proposed claims-based measures, such as inpatient safety measures and ambulatory care sensitive condition (ACSC) admissions measures, to our monitoring program to prevent ACOs from engaging in gamesmanship and manipulation of at-risk patients.

Comment: Many commenters suggested adopting a risk-adjustment strategy for measures that would account for beneficiary characteristics such as: geographic location, body mass index, socioeconomic status, education, severity or type of illness, race, ethnicity, gender, preferred language, disability status, or health literacy. One commenter recommended risk-adjusting outcomes measures in addition to process and patient experience measures. One of the commenters also noted that our proposed measure set provided no incentive for more accurate coding and failed to recognize that an aging population's health status is expected to deteriorate over time, not remain stable. One commenter was concerned about factors outside of an ACO may affect an ACO's quality measure performance, such as the patient's right to decide whether he or she will follow recommendations of health care professionals. One commenter requested clarification on how CMS will apply risk-adjustments when calculating ACO performance on specific quality measures.

Response: Risk adjustment is included for a number of the proposed measures, such as the ACSC measures, but is generally limited to age and gender. In addition, some measures include specific exclusions for patients, such as those in hospice, who may not benefit from an action targeted by the measure. Risk adjustment would also be used in the Risk-Standardized, All Condition Readmission measure, the details of which would be forthcoming in subregulatory guidance. We believe that our linkage of payment to accurate reporting requirements provides a strong incentive for complete and accurate reporting, since the quality performance standard must be met in order for an ACO to be considered eligible for shared savings. As discussed in section II.H.2. of this final rule, we may audit the quality measures data ACOs enter into the GPRO web interface by requiring the ACO to share beneficiary medical record information with CMS. As discussed in II.B. of this final rule, ACOs will also have to agree, as a condition of receiving any shared savings and participating in the program, that the quality data they submit to CMS is accurate, complete, and truthful. We believe that including a process to audit quality measures data and a certification requirement provides ACOs with an incentive to more accurately report quality measure data. In addition, we agree that the personal preferences of beneficiaries play an important role in their health behaviors. However, the lack of patient adherence may also represent a legitimate dimension of care, as it could be indicative of poor communication between ACO providers/suppliers and their patients. Beneficiary incentives are discussed further in section II.B. of this final rule.

We also received a number of comments on the specific measures proposed. We received the following comments on proposed measures 1–7: Patient/Caregiver Experience.

Comment: A number of commenters supported a prominent role for patient experience and health status in the measure set. One commenter applauded the inclusion of a measure on shared decision making while another advocated for additional shared decision making measures. One commenter was supportive of including measures of caregiver as well as patient experience. One commenter noted the importance of patient experience of care but cautioned that such measures are subjective, and do not always accurately measure the quality of care furnished and that ACO marketing materials could influence beneficiary responses.

Response: While we recognize the concern about patient subjectivity to surveys, we believe patients' perception of their care experience reflects important aspects of the quality of the care they receive, such as communication and patient engagement in decision-making, that are not adequately captured by other measures. As such, patient surveys are important complements to the other process of care and outcomes measures. For the

same reason, we intend to expand the quality measures over time to include more caregiver experience measures. In addition, we intend to retain some level of ACO marketing oversight, as discussed in section II.H.2 of this final rule, and will refine our processes over time as appropriate.

Comment: Many commenters supported using Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) surveys to measure patient experience but varied in their recommendation of which version to use. One commenter stated that CG–CAHPS and Hospital CAHPS (HCAHPS) do not include the desired shared decision making modules that are included in the draft Patient Centered Medical Home CAHPS (PCMH–CAHPS) and the Surgical CAHPS. Others supported the use of CAHPS but recommended adding additional measures to the domain. A few commenters suggested adding more care coordination and specialty care constructs to the patient/caregiver experience domain. One commenter suggested adding the new CAHPS cultural competence modules. One commenter stated that CAHPS did not adequately capture the team care experience of an ACO and suggested adding specific supplemental questions to CG–CAHPS.

Some commenters suggested other modifications to the proposed approach. One commenter suggested allowing ACOs to incorporate CAHPS constructs into existing surveys. Another commenter wrote that CMS should not allow ACOs to use existing experience tools because this approach would not produce comparable data and suggested that CMS require all ACOs to use the same, standardized tool, with the same sampling methodologies. Another commenter suggested a hybrid approach with some standardized measures but also with some flexibility for ACOs to replace survey items of no or limited relevance to their practice with other questions. One commenter recognized the importance of measures related to patient experience of care but recommended that they not be incorporated into the performance standard for the first agreement period. One commenter did not believe patient satisfaction should be used to assess ACO performance.

A few commenters cautioned CMS that there is limited experience with the CG–CAHPS tool, making it unfeasible for setting benchmarks initially and raising possible issues of its reliability and validity for ACOs. A couple of commenters suggested that survey information not be used to assess ACO performance until validated. One commenter recommended that until more proven measures become available, survey measures should include a ''control group'' of non-ACO FFS beneficiaries in the ACO's service area and be used for program monitoring and public information only. One commenter expressed doubt about whether the timeframe for implementing the survey and using the results to improve care would be feasible. One commenter stated that CG–CAHPS was not particularly actionable as many items included would not be under the control of ACOs and suggested visit-specific questions be used, such as those in the AMA Patient Experience Survey. A few commenters stated that CAHPS does not address communication, environmental factors, resource utilization, patient role in care, care coordination, or transition quality and suggested additional questions related to those areas. A few commenters found CAHPS both administratively burdensome and costly. One recommended CMS adopt a sampling approach to mitigate these factors, while another commenter recommended the survey be collected at CMS' expense. One commenter was concerned about duplicative CAHPS reporting through this program, PQRS and HCAHPS. Several commenters suggested methods other than CAHPS, or patient surveys in general, for collecting patient experience data. One commenter recommended CMS permit the use of other validated instruments, such as the American Board of Internal Medicine's condition specific patient surveys. Another commenter expressed concern that allowing ACOs to choose a survey instrument other than CG–CAHPS would limit the validity and utility of such data. One commenter recommended that the survey be tailored to the setting where care was received such as an inpatient rehabilitation unit or mental health.

Response: We believe the CG–CAHPS is the most appropriate version of CAHPS for ACOs, given the Shared Savings Program's primary care focus and the ambulatory care focus of the CG–CAHPS. We note, however, that our decision to require use of this survey instrument as part of the quality performance measures does not preclude an ACO from continuing to use other tools it may already have in place. We do not think HCAHPS is appropriate as a Shared Savings Program tool at this time, since not all ACOs will include a hospital. We recognize the PCMH–CAHPS currently in development may offer modules applicable to ACOs, so we may consider these modules, when available, in future rulemaking. While the CG–CAHPS is among the more recently developed CAHPS surveys, the modules have undergone field testing by a number of public and private organizations and are endorsed. There are already a number of users contributing experience with the CG–CAHPS, including regional collaboratives, member boards of the American Board of Medical Specialties, and a growing number of individual health plans and medical groups. In addition, national benchmark data are now available for the CAHPS Clinician & Group Survey through the National CAHPS Benchmarking Database. We also believe there is sufficient time to test the CG–CAHPS for ACO use.

In response to comments recommending that we add a care coordination and specialty care construct, we intend to add an Access to Specialists module as we think it is responsive to comments, will emphasize the importance of specialty care for patients served by the ACO, and complements our program focus on care coordination and our monitoring activities to ensure ACOs are not engaged in practices to avoid at risk patients. It also will align with the two-step methodology for assigning beneficiaries to ACOs, discussed in section II.E, of this final rule, which considers primary care services furnished by providers other than primary care physicians and will ensure that the CAHPS survey meaningfully assesses patient experience with ACO providers other than primary care physicians. This would mitigate the risk of issuing a survey to beneficiaries that does not necessarily reflect their care experience, which could be perceived as confusing and/or unduly burdensome.

Thus, we are finalizing the CAHPS modules listed in Table 1 for quality performance purposes as we believe they offer the best alternative for ACO patient experience of care measurement at this point in time. We are not finalizing the Helpful, Courteous, Respectful Office Staff module proposed for quality performance measurement and reporting or scoring purposes but note that this module is still a core part of the CAHPS survey to be collected and we will collect the data and feedback to ACOs for informational purposes only. We also believe there is evidence that CAHPS assesses important aspects of provider-patient interaction that can be influenced by an ACO's level of organizational support, training and incentive structure. These items may be combined with existing data in devising appropriate quality improvement

interventions as demonstrated by case studies and a guide available on the CAHPS Web site. We recognize that not all relevant areas of the patient experience are covered and will consider additional items in future rulemaking. We are sensitive to the data collection issues related to the patient experience survey and we have taken the commenters' implementation strategy suggestions under consideration. We will also consider the comments regarding adding additional CAHPS questions in the future. As described in section II.F.3. of this final rule CMS will fund and administer the survey for the first two calendar years of the Shared Savings Program, 2012 and 2013.

Comment: A number of commenters asked for clarification or made other specific comments regarding use of the CAHPS surveys for ACOs. One of these commenters recommended CMS: Use the six-point response scale, clarify if only the primary care CG-CAHPS should be used, and clarify how ACOs might add additional measures not included in the final measure set. One commenter expressed concern that various CAHPS tools do not recognize care provided by registered nurses and certified registered nurse anesthetists. One commenter stated that CAHPS data could include visits outside the ACO reporting period.

Response: We will consider comments regarding which CAHPS response scale is most appropriate for the Shared Savings Program and concerns that CAHPS data could include visits outside the reporting period and will release detailed instructions subregulatorily, outside of rulemaking. In response to the request that we clarify whether only the primary care version of the CG–CAHPS should be used for those modules from the CG–CAHPS, we note that the core CAHPS items proposed are identical for the CG–CAHPS primary care and specialty versions. The shared decision-making module, a supplemental module for both adult primary care and adult specialty care versions, is also identical in both versions. However, the health promotion and education module is a supplemental module from the adult primary care version only. With respect to the comment recommending that the included CAHPS modules reflect care furnished by registered nurses and certified registered nurse anesthetists, we recommend the commenter contact the measure steward directly with this suggestion.

Comment: Several commenters had varying recommendations about how the CAHPS data would be collected, including use of a web-based survey or cloud application and use of both mail and telephone as opposed to one or the other. A few commenters were concerned that mail and phone surveys would be unlikely to reach a large number of low-income beneficiaries with low English proficiency or with disabilities and urged us to allow on-site patient surveys. One commenter suggested providing detailed survey guidelines regarding the fielding of the patient/caregiver experience survey. One commenter noted that survey results are affected by survey mode and methodology; this commenter suggested CMS require ACOs to follow clear guidelines for survey administration in order to make data more comparable. A few commenters urged CMS to encourage patient surveys to be done by or under the supervision of the Regional Health Information Collaboratives. One commenter suggested oversampling to allow ACOs to internally report individual provider level feedback and to ensure that patients with chronic conditions, who would have the most ACO contact, are sufficiently represented. The commenter also suggested not restricting surveys to Medicare beneficiaries only, similar to HCAHPS. Finally, one commenter suggested a phased approach to implementing the survey.

Response: Because of these and other comments described in this final rule, we have decided to pay for the first two years of the survey in 2012 and 2013. We agree that survey mode and methodology can affect survey results and believe that, at this juncture, standardized administration and comparable results will be best achieved through the use of trained and certified vendors as is done with other CAHPS surveys administered to the Medicare population. We, too, are concerned about reaching low-income beneficiaries, as well as beneficiaries with limited English proficiency, chronic disease, or disabilities and will take these populations (and other relevant considerations) into account as we develop the sampling methodology for the CAHPS surveys. We will review carefully the results of the ACO patient experience of care survey in 2012 and 2013 to adjust and refine the sampling and/or survey methodology as we move forward.

We received the following comments regarding proposed measure 7: Health Status/Functional Status.

Comment: One commenter noted that this measure was appropriate for a survey item and recommended it be added to the CAHPS instrument. A few commenters thought patient survey tools should account for primary care services furnished by providers other than primary care physicians. A few commenters stated NQF #6, MA–CAHPS, was noted in the table, but NQF #6 is from the HP–CAHPS. Either way, the commenters expressed concern that while health status and functional status have been used for risk adjustment, these constructs are not currently used for accountability purposes in any pay for performance initiatives and may have limited value in determining high and low-performing physician group practices, particularly in small geographic areas, where patients have more limited choice in selecting providers. Many commenters advocated for stronger measures of functional status, including measures outside of CAHPS surveys, to help ensure providers with a higher proportion of patients for whom a cure is not available are not punished. A few commenters advocated adding functional status as a sixth domain. One commenter strongly supported measures of changes in functional status from admission and discharge but stated that the proposed measure is not measured from the patient or caregiver perspective and did not believe it is sufficiently objective. One commenter recommended development of ways to measure pre- and post-care health status of patients treated by ACOs.

Response: To clarify our original proposal, we intended to propose NQF #6. Health Status is intended to be self-reported in order to adequately represent the patient or caregiver perspective. Patient-reported outcomes, although subjective, provide valuable information not captured by other means, and many are well established and widely used with demonstrated reliability and validity. That said, we will consider suggestions for alternatives in the future.

We are also finalizing the health status survey as pay for reporting for all 3 years of the agreement period. While we agree with commenters that the information is important for improving the overall health and functioning of a patient population, we also recognize that it is not currently used for accountability purposes in any pay for performance. Therefore we will keep the measure as pay for reporting for the entire agreement period in order for ACOs to gain experience with the measure and to provide important information to them on improving the outcomes of the population they serve.

We received the following comments on proposed measures 8. to 23. Care Coordination.

Comment: Several commenters wrote in general support of the Care Coordination measures. One commenter supported the emphasis on care coordination but did not want this focus to be at the expense of specialty care. One commenter thought these measures were unclear and would be difficult to measure. One commenter suggested evaluating the incidence of ACSC admissions in each ACO. If the frequency of ACSC admissions in many ACOs is likely to be insufficient for statistical stability of admission rates, such instability should be considered before tying performance results to shared savings. One commenter believed CMS should reduce the number of measures until new and better care measures for this domain are developed and require reporting only (not performance) on all measures for the first 3-year agreement. However, another commenter recommended CMS add new quality measures to this category that define the responsibilities of both the sending and receiving provider and measure accountability and performance of these providers during patient care transitions. One commenter believed the proposed care coordination measures were inadequate to ensure that patient care is truly coordinated among providers and settings.

Regarding proposed measures 8–10. Risk-Standardized, All Condition Readmission; 30 Day Post-Discharge Physician Visit; and Medication Reconciliation, one commenter believed these measures were all based primarily on hospital performance and should be dropped. One commenter appeared to support electronic capture of the 30 Day Post-Discharge Physician Visit and Medication Reconciliation, but cautioned that only would be possible for readmissions and discharge visits that occurred among entities connected to that particular electronic medical record.

Response: We agree that care coordination is an important part of patient care and that sample size is an important consideration in measure selection. We also believe that accountability for patients, including knowledge of services rendered outside of an ACO, is important for achieving the three-part aim goals previously described. As a result, we note that all Shared Savings Program quality measures are intended to measure performance in relation to a defined set of assigned beneficiaries and not the performance of an individual entity, such as a hospital. Given the population focus of ACOs and refinements to the list of ACSC conditions, coupled with the phase in of these measures for performance, we believe that ACO assigned populations should be sufficient to reliably measure performance. We may consider including the additional measures suggested by commenters in the future.

Comment: Proposed Measure 8. Risk-Standardized, All Condition Readmission. A few commenters supported inclusion of measure 8 as proposed, but a few were not supportive. Some noted that this measure was not NQF-endorsed and that CMS had not provided specifications for this measure, making it impossible to evaluate the risk adjustment methodology or the measure exclusions, such as planned readmissions and transfers. A few commenters noted that there is already a readmission payment policy, and as a result, hospitals would potentially be penalized multiple times for the same readmission. Many commenters expressed support for a readmission measure but several of these commenters urged CMS to specify the measure to include only unplanned readmissions for heart attack, heart failure, and pneumonia. However, one commenter stated that CMS should not adopt the three CMS disease-specific all-cause readmission measures for heart attack, heart failure, and pneumonia currently reported to CMS because they leave out 85–90 percent of readmissions. One commenter stated that the proposed readmission measure lacked clinical credibility and could undermine quality improvement efforts. This commenter stated that the Affordable Care Act requires that readmission measures ''have exclusions for readmissions that are unrelated to the prior discharge'' and argued that the proposed measure failed to do this. This commenter also argued that certain readmissions related to the prior discharge are planned and unavoidable, such as planned chemotherapy. One commenter questioned how this measure would be used in an ACO context. Another commenter believed that review of patient medications within 24 hours of discharge/transition or communication with the patient within 72 hours of discharge/transition were better measures of care coordination. One commenter suggested the measure be changed to include readmission or admission to observation status within 30 days of discharge from an acute care hospital.

Response: Readmissions is an area in which we believe an ACO's coordination of care and accountability can have a significant impact in improving patient care and are finalizing this measure as proposed. While we recognize concerns that the measure has not been endorsed, this is one area in which we wish to exercise our discretion to include appropriate quality measures even if they have not been endorsed. We do not believe including this measure would be duplicative of any current readmission payment policy, since ACOs are a new concept and the Shared Savings Program is a new care model, and since this measure is not currently utilized in any other CMS quality reporting program. During the development of the proposed measures, we considered including the three disease-specific readmissions measures suggested by several commenters, but did not propose these measures for the reason another commenter noted: These types of readmissions represent only a small percentage of all readmissions. We recognize that certain readmissions are planned, unavoidable, and even advantageous to the patient, and will consider this prior to releasing specifications for this measure. That said, we also note that this measure has been under development and that finalization of this measure is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012. We are also finalizing the measure as a pay for reporting measure for the first two years of the program to allow more time for ACOs to gain experience with the measure and to redesign care processes to improve outcomes and reduce avoidable readmissions.

Comment: Proposed measure 9. 30–Day Post Discharge Provider Visit. One commenter suggested this measure could be captured through claims data, rather than through the GPRO web interface. A few commenters believed this measure should not only pertain to ACO providers. One commenter believed the 30-day period was too long and that a 5–7 day follow-up was necessary to avoid readmissions.

Response: We have decided not to include the measure at this time in response to comments regarding duplicity and reporting burden, as the medication reconciliation measure we are finalizing includes both the act of post-discharge medication reconciliation and a post-discharge provider visit. However, we would like to clarify the original proposal to collect this measure through the GPRO web interface rather than via claims data. In our proposed measures set development process, we concluded that although claims data would capture many post discharge visits, the GPRO web interface

would allow visits not discernable from claims, such as those that may be included in a bundled hospital payment, to be included in this measure. Although we are not finalizing the measure at this time, we will consider the comments received and revisit the appropriateness of adding this measure at a future time during future rulemaking.

Comment: Proposed measure 10. Medication Reconciliation. Several commenters commended including medication reconciliation in the measure set. One commenter stated that the 60-day time frame post-hospitalization appears to be a typographical error as NQF Measure #554 calls for a 30 day timeframe. One commenter recommended variations of the proposed measure, because the proposed measure is a self-reported, unidirectional measure. Another commenter proposed a self-reported adherence assessment measure should be included as well as measures that identify other barriers to medication adherence. This commenter also believed medication behavior assessment should not be limited to post-discharge but would also be indicated for all patients on chronic maintenance therapy, particularly those with diabetes, hypertension, coronary artery disease, or heart failure. A few commenters recommended that discharges from inpatient rehabilitation hospitals and units, long term care hospitals, skilled nursing facilities, and any of the multiple post-acute care outpatient settings be included in the final rule. One commenter stated this measure should include verification that medication reconciliation was conducted and documented prior to hospital discharge. A few commenters recommended a more limited time frame to avoid complications and readmissions; one mentioned a 3–7 day range. A number of commenters recommended deferring the introduction of this measure until EHRs are fully implemented and this measure can be captured electronically. One commenter recommended clarification that the medication reconciliation should be documented in a medical record rather than be a medication claim.

Response: The commenter that pointed out the error in the proposed rule is correct. NQF #554 is a 30 day post discharge medication reconciliation measure rather than a 60 day measure as we indicated in the measure description (76 FR 19572). The correct NQF number for the 60 day measure that we proposed is NQF #97. Accordingly, in this final rule, we are adopting NQF #97, the 60 day measure, in an effort to align with PQRS. Since this measure would be collected through the GPRO web interface, which will have ability to both accept manual data uploads and interface with an EHR as described in section II.F.4.b. of this final rule, we do not think this measure needs to be deferred until there is greater EHR implementation in the provider community. We recommend commenters direct comments regarding alternative time frames, care settings and other deviations from the endorsed specification to the measure steward. We will consider the other suggested medication-related measures and propose them through future rule making if appropriate.

Comment: Proposed measure 11. Care Transitions. One commenter generally endorsed measures related to transition plans of care, while others specifically endorsed this measure. One commenter recommended that this measure be eliminated as it is already captured via CAHPS, while another cautioned against adoption of any measure that requires chart abstraction. Another commenter expressed concern that this is not an objective measure and lacks evidence it improves outcomes. A few commenters requested that CMS clarify whether this is a survey measure or reported through GPRO. One commenter suggested CMS consider other care coordination measures that assess whether: the patient received a reconciled medication list upon discharge, the patient received a transition record with specified information, and the transition record was transmitted to the receiving provider in a timely manner.

Response: We are not finalizing this measure at this time in an effort to be responsive to comments about reporting burden. We recognize this measure is typically collected within 48 hours to six weeks after discharge via phone or mailed survey. In exploring options for operationalizing this measure in an ACO context, we recognize that it would be difficult to require this measure for an ACO that does not have a hospital, as it could require substantive infrastructure, education, and development to have an ACO disseminate the survey questions to patients timely post-discharge and report the results to CMS. Nevertheless, we continue to believe that assessing care coordination, and in particular care transitions, is an important aspect of evaluating the overall quality of the care furnished by ACOs. One way we will do this is by including an access to specialists module in the CAHPS survey as previously described. We also intend to continue exploring ways to best capture ACO care coordination metrics as suggested, including the proposed measure, and will consider adding new care coordination measures for future years.

Comment: Proposed measures 12–18. Ambulatory Care Sensitive Conditions Admissions. Several commenters expressed concern about the use of various AHRQ Prevention Quality Indicators (PQIs) for the Ambulatory Care Sensitive Conditions (ACSC) Admissions measures as these are designed as screening tools rather than quality measures and are not adequately risk-adjusted. A few of these commenters thought the PQIs might be useful for monitoring but not for inclusion in performance scores, since they could inadvertently drive underutilization. One commenter suggested evaluating the incidence of ACSC admissions in each ACO and if the size of many ACOs' enrollment is insufficient to assure that these measures are statistically stable, such instability should be considered before tying performance results to shared savings. One commenter suggested developing a methodology to address how measures for ACOs with small eligible populations (for example N<30) can be reliably and fairly scored. Two commenters recommended we consider consolidating measures with small sample sizes into one measure at least for scoring purposes. One commenter believed beneficiary compliance to be outside the provider's control and recommended that CMS monitor these measures rather than include them in the performance score.

One commenter supported the intent of ACSC: Congestive Heart Failure (proposed measure 15) but stated there are technical issues with the measure in that it may not accurately capture patients with CHF. This commenter urged CMS to remove monitor implementation of this measure to ensure its reliability. We did not receive any comments on ACSC: Dehydration (proposed measure 16). One commenter wrote in support of ACSC: Bacterial Pneumonia (proposed measure 17). Another commenter stated that ACSC: Bacterial Pneumonia assumes that administrative claims can identify preventable cases of pneumonia, fails to recognize that the pneumonia vaccine has limited effectiveness, and does not adjust for regional differences in patient and environmental characteristics associated with risk for pneumonia. One commenter wrote in support of ACSC: Urinary Infections (proposed measure 18).

Response: We note that the AHRQ PQIs for Ambulatory Care Sensitive Condition admissions are well-established as indirect measures of access to and performance of timely and effective primary care services. That is, timely and effective care for managing patients' chronic conditions should result in fewer hospital admissions for these admissions. These were among the measures recommended by major provider groups in Listening Sessions conducted by CMS to inform the rule-making proposals. We recognize the commenters' risk adjustment concerns and believe that the adjustment for age and sex included in these measures establishes a fair baseline for comparing ACO performance to national benchmarks, so that both very high and very low rates can be investigated. The ACSC admissions represent common conditions among Medicare FFS beneficiaries, but we recognize the concern of small numbers of admission events. We have accounted for this concern in our selection of final ACO quality measures to include those PQIs that we believe are most important as indicators of ACO care coordination and remove those that we believe are still important but may have sample size issues or are less central to ACO goals. We are not finalizing the following ACSC measures for quality performance purposes but may still consider calculating them from claims for monitoring and informational purposes: diabetes, short-term complications (proposed measure 12); uncontrolled diabetes (proposed measure 13); dehydration (proposed measure 16); bacterial pneumonia (proposed measure 17); and urinary infections (proposed measure 18). We are finalizing the ACSC measures for COPD (proposed measure 14) and heart failure (proposed measure 15). Once we have actual ACO performance data on the measures, we will review again to determine if sample size is truly an issue in the ACO context and will address in the future if needed. We suggest that commenters contact the measures steward directly regarding any technical issues identified with these measures. Finally, we do not believe it would be appropriate to combine measures with small sample sizes into one measure, as one commenter suggested. Such combination would require further testing and coordination with the measures steward. Additionally, we are unclear how an ACO could take action based on a consolidated ACSC measure score that does not distinguish between types of ACSC events.

Comment: Proposed measures 19–23. Care Coordination/Information Systems. One commenter wrote in support of all 5 of these measures. Another recommended CMS require ACOs to implement the use of electronic medical records as soon as practicable. Many commenters wrote in support of a single measure of EHR program participation, such as proposed measure 19. Percent of all Physicians Meeting Stage 1 Meaningful Use Requirements or proposed measure 20. Percent of PCPs Meeting Stage 1 Meaningful Use Requirements. A number of commenters recommended removing these measures for a variety of reasons. A few commenters recommended CMS remove these measures or collect them only for monitoring purposes because they are structural measures and not necessarily accurate indicators of quality performance. Another commenter echoed this recommendation and added that the incentive should not be based upon the tools or processes used by an ACO but rather the outcomes achieved by the ACO. A few commenters stated that adoption of health information technology is already the subject of penalties and incentives under the EHR Incentive Program and including these measures for the Shared Savings Program is redundant. A few commenters believed it unfair to penalize ACO providers for not meeting meaningful use in advance of the penalty phase of the EHR Incentive Program. One of these commenters noted that these measures are not core measures for the EHR Incentive Program and meeting the proposed requirements would be feasible only for ACOs that already have experience with a robust EHR. One commenter believed certain EHR Incentive Program measures were susceptible to inaccurate reporting, such as whether medication reconciliation is performed.

A few commenters recommended proposed measures 19 (Percent of All Physicians Meeting Stage 1 Meaningful Use Requirements) and 20 (Percent of PCPs Meeting Stage 1 Meaningful Use Requirements) be dropped or that CMS should exempt specialists. One commenter thought Stage 1 Meaningful Use measures made it difficult for specialists to achieve meaningful use, while another objected to requiring specialists to report on primary care-based measures. One commenter asked CMS to consider how specialists, who are permitted to contract with multiple ACOS, would be able to communicate electronically across various ACOs, who may be using different EHRs that are not interoperable. One commenter requested that the ACOs' EHR-related measures not be limited to the categories of providers designated as EPs under Stage 1 of Meaningful Use.

A few commenters requested clarification of the definition of clinical decision-support in proposed measure 21 (Percent of PCPs Using Clinical Decision Support), and one commenter urged CMS to include cardiovascular imaging decision support tools in the measure. Proposed measure 22 (Percent of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program) and proposed measure 23 (Patient Registry Use) each received one comment of support.

Response: We considered these comments in finalizing our measures set and have decided to finalize only proposed measure 20 and expand it to include any PCP who successfully qualifies for an EHR Incentive Program incentive rather than only including those deemed meaningful users. One reason for retaining this measure is that we believe it is important to encourage EHR adoption as a means for ACOs to better achieve the goals of the three-part aim, recognizing that some organizations may currently be achieving better quality outcomes using EHRs, even if they are not yet considered ''meaningful users,'' than organizations that have not yet adopted such technology. To this end, we recognize that first-year Medicaid EHR Incentive Program participants can earn an EHR incentive for adopting, implementing, or upgrading an EHR, and do not need to be ''meaningful users'' in order to earn an incentive, and would like to include such EHR participants in this measure. A second reason for retaining this measure but not proposed measure 19, percent of all physicians meeting Stage 1 HITECH Meaningful Use Requirements, is that we recognize some ACOs may be comprised of PCPs only. An ACO's score on proposed measures 19 and 20 would be the same if the ACO is only comprised of PCPs. As a result, the use of both measures could be considered redundant. The third reason for finalizing proposed measure 20 with modification is that it is a structural measure of EHR program participation that is not measured in any other program, and therefore is not duplicative of any existing measures. In addition, CMS can calculate the measure based on data already reported to the EHR Incentive Program, such that no additional reporting would be required by ACOs other than what EPs have already reported. Overall, we believe relaxing this measure definition is more inclusive and promotes

participation, while still signaling the importance of healthcare information technology (HIT) for ACOs.

Regarding the decision not to finalize the other proposed Care Coordination/ Information Systems measures (that is proposed measures 21–23), we have removed these measures based on commenters' recommendations and in an effort to pare down the proposed measures set to those measures that will have the most impact and are most aligned with ACO goals. Our intent is to align the Shared Savings Program measures with the EHR Incentive Program measures, however since we are not incorporating the EHR Incentive Program or eRx Incentive Program incentives under the Shared Savings Program, as discussed in section II.F.5. of this final rule, we have decided not to finalize EHR and eRx structural measures that may be considered redundant. For instance, we recognize that some ACOs may be comprised predominantly of primary care physicians, which would make proposed measure 19 largely redundant of proposed measure 20.

In response to the comment on proposed measure 21. Percent of PCPs Using Clinical Decision Support, to clarify, the measure proposed was an EHR Incentive Program core measure for clinical decision support. We have removed this measure from the final set, since it is included in the meaningful use requirements and could be considered redundant. Some of the EPs who successfully qualify for an EHR incentive payment are meaningful users of HITECH, and clinical decision support is one of the requirements to be considered a meaningful user. Similarly, we did not finalize proposed measure 22 (Percent of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program), since EPs cannot earn both an eRx Incentive Program incentive and a Medicare EHR Incentive Program incentive. As a result, any measures that reflect successful incentive qualification for the eRx and Medicare EHR incentives would conflict with one another. In addition, we believe there is some redundancy between proposed measures 21 and 22 with proposed measure 20. Percent of PCPs Meeting Stage 1 Meaningful Use Requirements, since clinical decision support and electronic prescribing are part of the meaningful use criteria included in proposed measure 20., which we are finalizing with minor modifications as previously described.

We are not finalizing the Patient Registry Use measure (proposed measure 23), since it is not a required, ''core'' measure in the EHR Incentive Program's meaningful use criteria. We have concerns that, by requiring this measure, we will inadvertently provide an incentive for ACOs to make an optional, EHR Incentive Program ''menu set'' measure a ''core'' measure for their ACO providers/suppliers who are EPs. We also recognize that patient registry use is fundamental to measuring, improving and reporting quality measures so we expect that most, if not all, ACOs will have some form of patient registry use already in place to support quality measurement and improvement activities. As a result, we believe this measure is unlikely to provide an incentive for more widespread adoption of EHRs or registries or improved ACO performance.

Comment: Proposed measures 24. Health Care Acquired Conditions Composite and 25. CLABSI Bundle. One commenter endorsed measures related to hospital-acquired conditions and patient safety, but many commenters stated that hospital-based measures should be removed or were not applicable to ACOs that do not include hospitals as ACO participants. One commenter stated that the information exchange required would generally not be in place for ACOs without hospitals, and another thought these measures were duplicative of IPPS reporting. Others stated that hospitals were already being held accountable through the hospital value-based purchasing program and that, in many markets, an ACO simply wouldn't have the ability to impact the various hospitals where an ACO's members might receive treatment. Commenters proposed various alternatives: That ACOs without hospitals be exempted from reporting on these measures; that hospital measures be made voluntary; that these be dropped completely; or that we use process measures that are already widely used in the hospital value-based purchasing program until true population-based outcomes measures are available. Several commenters expressed concern about including the HAC composite but supported inclusion of the CLABSI bundle until better ACO patient safety measures are developed. One commenter thought it duplicative to have two different measures of central line infections and preferred the CLABSI bundle as a more reliable and valid measure. Regarding the proposed method of data submission, one commenter noted the difficulties of using claims data to accurately detect healthcare acquired conditions and supported the CDC National Healthcare Safety Network (NHSN) surveillance data as a more reliable source. One commenter recommended CMS apply the recently released regulations specifying that state Medicaid programs may use more comprehensive approaches to payment adjustment to ACOs. One commenter stated some hospital acquired conditions can be reduced but not eliminated and programs that expect elimination may cause providers to avoid caring for high-risk patients and recommended identification of evidence-based exceptions, development of alternative systems to encourage providers to adopt processes to reduce HACs, and systems to measure process steps taken.

Proposed measure 24. Health Care Acquired Conditions Composite. A few of commenters wrote in support of this measure; one recommended CMS only score the measure on an ''all or nothing'' basis to eliminate rewards for preventable medical errors. One commenter argued that measurement alone would motivate improvement as long as scores are transparent and visible. Another commenter recommended this composite only be used for monitoring and not for performance scores.

Many commenters expressed concerns about including the HAC composite, most commonly on the grounds that it is untested or because it is a hospital-based measure. A few commenters stated that the proposed composite HAC measures lack clarity and do not provide useful or timely information to improve performance. These commenters were concerned about the measure being a compilation of nine CMS HACs combined with an AHRQ Patient Safety Indicator which is itself a composite of eight measures, some of which are only slightly different from other proposed components (for example pressure ulcers and decubitus ulcers are both included). These commenters were concerned about how risk adjustment would be handled in this composite, since sicker patients are at higher risk for HACs. These commenters were also concerned that the data could be submitted from either administrative/claims data or NHSN and that the resultant measure including both sources has not been validated. These commenters recommended that CMS use the HAC measures individually as separate measures and not a composite as currently defined in the Hospital Inpatient Quality Reporting Program; use CLABSI from NHSN with data submitted as a separate patient safety measure; and delete AHRQ PSI #90 since it overlaps with several HAC measures and imposes redundant, duplicative effort. Another commenter

with similar concerns recommended inclusion of the first five HAC measures along with additional NQF measures such as, patient death or serious injury associated with medication errors, or failure to follow up on or communicate clinical information as soon as practicable.

Commenters were also concerned that: the complexity and lack of validation for the composite would discourage organizations or groups from participation; risk adjustment is needed since sicker patients have a greater chance for these events; and many of the HACs are low-incidence complications that have not been tested for rate-based comparisons. One commenter opposed the inclusion of accidental puncture or laceration and iatrogenic pneumothorax, arguing that including measures for rare complications is ineffective and may result in unintended consequences. This commenter stated that it is difficult to identify statistically significant differences rather than random variation in the data and raised concern that measuring such rare events could drive increased use of less safe procedures such as femoral catheterization. A few commenters recommended this measure be used for monitoring and not be used as part of the performance score. One commenter stated that there are ambiguous coding guidelines regarding inadvertent laceration or puncture not considered to be accidental (for example serosal tears) and recommended CMS field test patient safety measures prior to adopting them for the Shared Savings Program. Another commenter noted that the proposed ACO HAC Composite includes CLABSIs rather than vascular catheter-associated infections, consistent with reporting requirements in the Hospital Inpatient Quality Reporting program. However, this commenter urged CMS to further align measurement requirements and use CLABSIs across programs in order to reduce duplicative reporting burden and to support the use of what the commenter believed to be superior quality data.

A few commenters noted that proposed measure 25. Health Care Acquired Conditions: CLABSI Bundle is the CDC National Healthcare Safety Network (NHSN) process measure of central line insertion practices and questioned how it would be possible to measure this based on claims data. The commenters stated that the measure is very labor intensive, and is not in widespread use even in NHSN, which means there are minimal baseline data. The commenters recommended that this measure not be included given the lack of baseline data, the labor intensity of the required chart abstraction, and the number of proposed ACO quality measures. Another commenter preferred this measure over the proposed HAC Composite.

Response: Medical errors are a major source of morbidity and mortality in the United States, and patient safety initiatives that reduce the number of these events are a critical focus for CMS and the Department. However, we recognize that not all ACOs will have participating hospitals, but, for those ACOs that do have hospitals, we do not believe this approach is duplicative of hospital value-based purchasing program efforts, which calculate such measures at a hospital patient population level and not at an ACO assigned beneficiary population level. We also recognize that some HACs may be reduced but not eliminated, as one commenter noted. Reporting remains an important issue for effectively tracking health care acquired conditions. Measuring ACO performance on HACs would potentially serve as an incentive to improve reporting. We agree many of the hospital acquired conditions are rare events and proposed the composite in an effort to produce a larger, more meaningful sample size, since ACOs will have smaller populations and even fewer events than would a hospital. However, we recognize there are challenges with combining claims and surveillance-based measures that have different calculation methodologies into one measure. There are also challenges with using hospital-reported measures based on aggregate, all payer data, as is the case with measures reported to the NHSN, particularly for ACOs that do not include hospitals. Upon further consideration of our proposal, we agree with the suggestion that, if these measures were to be finalized, we should break out the components and score the measures individually. We recognize there are operational complexities combining endorsed measures that reflect different population bases and have different timeframes, data sources and risk adjustment methodologies. In addition, we realize that combining these measures may result in a larger number of incidents in the measure numerator, due to the larger sample size, but may not result in more meaningful information for an ACO. That is, in combining the HACs into one measure, the ACO cannot discern which HACs are of concern and which are not, whereas measuring the HACs individually would provide such information.

That said, we have decided not to finalize these measures at this time. However, we may consider claims-based HAC measures that can be calculated at an ACO assigned beneficiary population level for quality monitoring purposes, regardless of whether an ACO includes a hospital. That is, we would determine from claims whether any ACO-assigned beneficiaries who had been hospitalized (regardless of whether the hospital is an ACO provider/supplier) experienced a HAC. We believe the approach of considering claims-based HAC measures that can be calculated at a patient level emphasizes the importance of monitoring HACs among an ACO's assigned beneficiary population but eliminates reporting burden and operational complexity, particularly for those ACOs that do not include a hospital. We would not calculate the CLABSI Bundle, even for monitoring purposes, at this time as this measure can only be calculated from NHSN surveillance data, as one commenter clarified. Since NHSN data are hospital-reported, all-payer data, we are unclear at this time how to translate such data to a Medicare FFS ACO population, particularly when ACOs do not include a hospital. However, we will continue exploring how to leverage NHSN data in the Shared Savings Program.

Comment: Proposed measures 26–34. Preventive Health. A few commenters wrote in general support of preventive care measures while one commenter recommended that all preventive health measures should be dropped until they can be studied further. One commenter suggested CMS work with CDC to add additional prevention measures as the program matures.

Response: We believe preventive health is critical to reducing chronic, costly conditions, and that primary care is critical to the ACO model of care. As a result, we believe it is important to retain preventive health quality measures in the Shared Savings Program. However, we will monitor these measures and work with the measures community in an effort to ensure we are using the most appropriate, high impact measures.

Comment: Proposed measures 26 and 27. Influenza Immunization and Pneumococcal Vaccination. Several commenters wrote in support of one or both of these measures particularly given the burden of death, disease and high cost care resulting from pneumococcal disease and influenza among the elderly. One commenter stated that these measures are not geared towards population health and should be removed. One commenter recommended that providers not be penalized for vaccine shortages. Another commenter recommended

deferring introduction of these measures until EHRs are in widespread use because vaccine administration would be difficult to document if the vaccine was received outside of the ACO. Another commenter noted the burden of using EHR data to populate GPRO and suggested CMS instead consider the survey-based measure from NCQA HEDIS, which could be added to the CG–CAHPS. One commenter suggested updating the pneumococcal vaccination measure to include the new ACIP recommendations for pneumococcal vaccine for patients age 5–64 that have a high-risk condition.

Response: We believe vaccinations are important to population health, particularly in the Medicare population, and are finalizing the proposed measures with minor modification as discussed later in this final rule. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention states effectiveness estimates for vaccines range from 50 percent to 80 percent for prevention of pneumonia among immunocompetent older adults and adults with various underlying illnesses.[2] The CDC has also shown that elderly citizens vaccinated against influenza have reductions in the rates of hospitalization and death from influenza, as compared with the rates in unvaccinated elderly persons. These measures were not intended to penalize providers in cases of vaccine shortages. Commenters should contact the measures stewards regarding such concerns.

The CAHPS questions relevant to health care services are intended to assess the patient's experience with care furnished in the ACO rather than whether the ACO providers are actively tracking immunization status. Since ACOs are charged with better coordinating and improving care, we believe these immunization measures should be ACO-reported not patient-reported. Our ACO GRPO reporting process uses patients' claims data to the extent that they are available when calculating the measure, thus reducing the burden on providers for reporting on their population while allowing the ACO to update the numerator with information from its clinical or administrative systems, such as patient-reported information.

Additionally, in response to other comments requesting that we align measures with those used in PQRS and the EHR Incentive Program, as discussed in section II.F.5. of this final rule, we have finalized the pneumococcal vaccination measure to reflect NQF #43 instead of #44. Both measures have the same denominator population—patients over the age of 65—and reflect the same outcome, whether pneumococcal vaccination was obtained in the previous 10 years; however, we believe NQF #43 offers an advantage to ACOs over NQF #44 in that a provider collects NQF #43 through discussion with the patient, whereas NQF #44 requires medical chart abstraction. Because of the level of effort required to obtain a 10 year chart abstraction (for purposes of NQF #44), the decision was made to use NQF #43, which can be collected at the point of care during a current patient visit and reported electronically through the GPRO web interface. We believe the use of this measure would help address the general comments regarding reporting burden and would align with quality measures used in other programs, such as PQRS.

Comment: Proposed measure 28. Mammography Screening. Several commenters noted that this measure was not aligned with professional guidelines that do not support routine mammograms for women 40–49 and recommended shared decision making between woman and provider. Some of these commenters also noted that guidelines recommend screening for women until age 74, not 69 as proposed. One commenter favored inclusion of women 40–49 but stated that the upper age limit should be at 5 years of life expectancy. One commenter stated that this measure should be eliminated because it has potential for the unintended consequence of interfering with a woman's right to refuse mammography until age 50, by measuring the quality of an ACO's care based on whether she received biennial exams starting at 40. One commenter thought the measure should begin at age 40, since this age is included in health plan coverage and as a measure of provider counseling given to the woman. Another commenter recommended that this measure be excluded because the denominator population (women, 40–69 years of age) is comprised primarily of patients who are not Medicare beneficiaries.

Response: We are finalizing the measure as proposed. The proposed measure follows guidelines established by NCQA and endorsed by NQF. We recognize that the age 40–49 category applies to a small percentage of Medicare beneficiaries, however early detection allows women to obtain timely treatment and potentially lead a longer, healthier, life. We believe early preventive health is important for deterring many of the chronic conditions and illnesses more prevalent later in life that are more specific to the Medicare population. Additionally, this age range aligns with preventive health measures with similar age ranges used in other CMS quality programs. We also appreciate the recommendation to extend the age range to 74, however the current measure specification is for years 40–69. We expect that the specifications for the endorsed measures may be updated to reflect the change in clinical guidelines, at which time we would also adopt such specifications.

Comment: Proposed measure 29. Colorectal Cancer Screening. We did not receive any comments on this proposed measure.

Response: We will finalize this measure as we believe colorectal cancer screening is an important component of preventive health in the Medicare FFS population.

Comment: Proposed measure 30. Cholesterol management for Patients with Cardiovascular Conditions. One commenter wrote in support of this measure.

Response: We note that the correct title of the measure corresponding with the NQF number proposed (NQF #75) is: Ischemic Vascular Disease: Complete Lipid Profile and LDL Control <100. We have finalized this measure to reflect the correct title and also added an Ischemic Vascular Disease subcategory in the At Risk Population domain. This measure also aligns with other cardiovascular disease prevention initiatives that are priorities for CMS, CDC, and HHS, such as the Million Hearts initiative.

Comment: Proposed measure 31. Adult Weight Screening and Follow-up. One commenter expressed concern that this was a process measure that does not measure actual weight management.

Response: We believe the processes of weight and BMI screening and follow-up are important steps for preventing and reducing obesity and complications related to other chronic conditions in which weight plays a factor. BMI measurement can also be considered an intermediate outcome, since BMI can be used to monitor patients' progress with respect to weight reduction as well as weight gain that can exacerbate chronic conditions. Therefore, we are finalizing this measure.

Comment: Proposed measure 32. Blood Pressure Measurement. One commenter stated that a measure of the percentage of patients with uncontrolled blood pressure did not represent a best practice of care. A few commenters

[2] Centers for Disease Control and Prevention. Influenza and Pneumococcal Vaccination Levels Among Adults Aged greater than or equal to 65 Years—United States. MMWR 1998 Oct 2; 47(38); 797–802.

questioned the meaningfulness of this measure; one urged CMS to go beyond structure and process measures to measures that solidly address clinical appropriateness and overuse. One commenter suggested deleting this blood pressure process measure, because we also proposed a blood measure level measure.

Response: Blood pressure measurement for patients with diagnosed hypertension is a best practice according to clinical guidelines; however the measure community recognizes the high rate of compliance and the need for even greater quality improvement. We agree with the suggestion to remove this measure, since the AMA–PCPI is retiring this measure (NQF #13), and because it is similar to proposed measure 58. Hypertension: Blood Pressure Control (NQF #18).

However, we believe blood pressure measurement is an important preventive health measure and therefore have included ''Proportion of adults 18 years and older who have had their BP measured within the preceding 2 years,'' in the final measures set, consistent with the measure that has been proposed for the PQRS for 2012. The measure we are finalizing also aligns with the Million Hearts Initiative and blood pressure measurement standards of care recommended by the USPSTF and the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. We believe this measure is more appropriate for the Preventive Health domain of the Shared Savings Program than the measure proposed as it is a quality measure intended for patients without diagnosed hypertension whereas the proposed measure was intended for BP management for patients with diagnosed hypertension. Similar to the proposed measure, the measure we are finalizing targets a Medicare FFS population age 18 and older, requires two face-to-face provider encounters for assigned patients, and would be reported via the GPRO web interface.

Comment: Proposed measure 33. Tobacco Use Assessment and Tobacco Cessation Intervention. Several commenters wrote in support of the tobacco use measure. One commenter proposed use of NQF Measure #27 as a stronger measure of cessation efforts. One commenter questioned the fairness of holding ACOs responsible for patients who might choose to continue using tobacco. One commenter expressed concern that this measure could be gamed and suggested excluding or modifying the measure. One commenter recommended replacing this measure with PQRS measure #226.

Response: Tobacco use is harmful to patient health, but among diabetics, it is particularly dangerous as it increases the risk of complications, and we are therefore including this measure in the final set. To substantially lower the risk for cardiovascular and stroke events, it is critical that the specified tobacco use assessment and cessation goals are achieved. This quality measure aims to encourage even greater engagement by physicians and their patients in achieving tobacco free status. We recognize the potential for gaming and will monitor this measure closely, for instance, through the GPRO audit and validation process described in section II.F.4.b. of this final rule. We will consider suggestions for other measures in the future. We also note that at the time of our proposed rule the PQRS measure number was ''TBD'' and has since been numbered 226; thus, the measure we proposed and are including in the final measure set for the Shared Savings Program is the same measure used by PQRS.

Comment: Proposed measure 34. Depression Screening. A few commenters wrote in support of the depression screening measure. One commenter stated that this measure would require significant changes in primary care workflow, even though it has not been linked with improved chronic disease outcomes in clinical trials. One commenter recommended modifying the measure to incorporate elements of NQF #17 that specify screening, monitoring, and reassessment with the Patient Health Questionnaire. One commenter recommended CMS replace this measure with other measures or expand it to include other mental health assessment tools. Another commenter stated that while several useful tools are available in the public domain, many lack standardization of scoring and data collection modalities, or lack sufficient normative data and condition-specific benchmarks useful for interpreting health scores and reducing interpretation bias. In addition, the commenter stated, many publically available health measures lack culturally validated translations for non-English speaking patients.

Response: We disagree with the comment that depression screening has not been linked to improved chronic disease outcomes in clinical trials. In a systematic review of the evidence, the USPSTF concluded that depression screening significantly improves patient outcomes. (*http://www.ncbi.nlm.nih.gov/books/NBK36406/*) Another study found that the presence of depression is associated with reduced compliance with treatment.[3] Because patients in whom depression goes unrecognized cannot be appropriately treated, systematic screening has been advocated as a means of improving detection, treatment, and outcomes of depression. As a result, we are finalizing this measure in order to encourage ACOs to adopt system changes that ensure timely identification and adequate treatment and follow-up if needed. Since the NQF #17 measure suggested is Hypertension Plan of Care we believe the commenter was actually referring to NQF #712, Depression Utilization of the PHQ–9 Tool.

Comment: Proposed measure 35. Diabetes Composite (all or nothing scoring) and 52. Coronary Artery Disease (CAD) Composite (all or nothing scoring). A few commenters wrote in support of these measures. A few commenters stated opposition to scoring these measures in an ''all-or-nothing'' manner. Other commenters cautioned against use of both the composite measures and counting the components of the composite as individual measures because of resultant ''double counting.'' A few commenters recommended using only the individual measures to allow ACOs to target processes for improvement but others recommended retaining only the composite.

A few commenters recommended CMS replace the diabetes composite measure proposed with NQF measure #0729 and use the specifications for measure #0729 for proposed measures 36–39 and 41. One commenter recommended CMS include microalbumin screening in the diabetes composite measure as well as an individual measure. One commenter questioned the fairness of holding ACOs responsible for patients who might choose to continue using tobacco, under the diabetes composite. One commenter recommended replacing either the diabetes or CAD composites with the Optimal Vascular Care Composite (NQF #0076).

Response: To clarify, the diabetes composite measure proposed is the Optimal Diabetes Care composite, NQF #0729, as one commenter suggested. At the time of the proposed rule, this measure was pending NQF endorsement. As a result, we proposed similar NQF numbers for the components of this composite to provide the public the opportunity to review and comment on similar and/or

[3] DiMatteo MR, Lepper HS, Croghan TW. Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. Arch Intern Med. 2000 Jul 24;160(14):2101–7.

related component measures. Since the time of proposed rulemaking, the measure has been endorsed and numbered #0729. We also note this composite is currently NQF-endorsed with 5 components, of which microalbumin screening is not included, so we advise the commenter that supported inclusion of this measure to contact the measure steward directly about the addition of other components. Although we appreciate that there are concerns about all-or-none scoring, there are also advantages. For instance, AMA–PCPI states that the ''all-or-none method is the most patient-centric approach and provides the most opportunities for improvement, especially if the individual components are reported out separately.'' (*http://www.ama-assn.org/resources/doc/cqi/composite-measures-framework.pdf*)

We also understand concerns about the redundancy of scoring both the composites and individual measures and are finalizing the proposed diabetes and CAD composites, with modification to the CAD composite as described later in this final rule, and are not finalizing the individual proposed measures that were also within the proposed composites, consistent with the AMA–PCPI statement cited previously. However, we will report back to ACOs their results on individual measures within the composites in addition to their overall composite measure score. We believe the diabetes and CAD composites raise the bar for diabetes and CAD care, consistent with Shared Savings Program goal of improving quality of care, by providing an incentive for ACOs to ensure that a number of important care processes are performed for diabetic and CAD patients, and that appropriate outcomes are achieved. In contrast, the individual measures would award points if only some of the processes are performed and some outcomes are achieved. We recognize the concern about holding ACOs accountable for patient choices such as continued tobacco use. However, since tobacco use causes greater complications among diabetics, we believe the tobacco use component of this composite measure will incentivize greater provider involvement in smoking cessation counseling.

Comment: Proposed measures 35 and 39. Diabetes Mellitus: Aspirin Use. One commenter wrote in support of this measure. One commenter stated that these measures are not evidence based as aspirin should be given to patients with diabetes only after consideration of their 10-year risk of a significant coronary event in accordance with current USPSTF and American Diabetes Association guidelines. One commenter considered this measure of limited value and noted that it only applies to those with diabetes and ischemic vascular disease but is not included as a measure for those with just coronary artery disease.

Response: To clarify, we proposed the Minnesota Community Measurement ''Optimal Diabetes Care'' composite for its up-to-date research, extensive testing, and relevance to the Medicare FFS beneficiary population, as discussed previously. The composite measure received NQF endorsement in March 2011, too late for this information to be included in the Shared Savings Program proposed rule. Regarding the aspirin use component of proposed composite measure 35, which we also proposed as individual measure 39, the recommendation for aspirin use for diabetics with known cardiovascular disease is based on American Diabetes Association guidelines for daily aspirin use.[4] Evidence no longer supports daily aspirin for all diabetics age 40 and older, and, as a result, the aspirin component of the composite measure only includes diabetic patients with known cardiovascular disease.

We are finalizing diabetes aspirin use as part of the diabetes composite (proposed measure 35) but are not finalizing it as an individual measure at this time. Instead of the individual aspirin use measure, we are finalizing Ischemic Vascular Disease: Use of Aspirin or Another Antithrombotic (NQF #68), which we believe is a broader measure that is more aligned with Departmental efforts to improve cardiovascular care and with other agency programs, such as PQRS. Both proposed measure 39 and NQF #68 measure aspirin or antithrombotic use in beneficiaries diagnosed with ischemic vascular disease (IVD), use a common set of ICD–9 codes to define the condition, and are calculated for Medicare FFS beneficiaries age 18 and older. However, we believe the IVD measure is more appropriate as an individual measure, since it is intended for the entire IVD population, rather than only those with IVD and diabetes, which the diabetes composite measure already captures.

The IVD measure also includes use of other antiplatelet medications, which we believe reduces the need for a separate CAD: Oral Antiplatelet Therapy Prescribed for Patients with CAD measure, as discussed in more detail later in this final rule in connection with proposed measure 53. Thus, we believe the IVD measure reduces the burden of quality measure reporting for ACOs, since it is one GPRO measure that captures the data that would otherwise have been required be reported via 2 separate measures. It also aligns with PQRS efforts for 2012, the Million Hearts initiative, and the other IVD measures we are finalizing in this rule.

Comment: Proposed measures 36 and 40. Diabetes Mellitus: Hemoglobin A1c Control and Hemoglobin A1c Poor Control. A few commenters recommended that, in order to pare down measures, CMS retain only one of these measures as there is some overlap. One commenter recommended CMS use age limits for these measures.

Response: We note that these measures do address somewhat different aspects of diabetes control. HbA1c Control targets good control in patients, with an aim of monitoring to keep levels in range, while HbA1c Poor Control targets patients whose diabetes is poorly-controlled and may require additional intervention. Accordingly, we believe it is appropriate to retain both measures. Although we are not finalizing proposed measure 36 in this final rule, HbA1c Control is part of the all or nothing diabetes composite measure under proposed measure 35. We suggest that the commenter concerned about age limits contact the measure steward directly.

Comment: Proposed measure 38. Diabetes Mellitus: Tobacco Non Use. A few commenters believed this measure was unnecessary as it was duplicative of proposed measure 33. Tobacco Use Assessment and Tobacco Cessation Intervention or suggested that the measure be broadened to all tobacco users, regardless of diagnoses. One commenter expressed concern that this measure could be gamed and suggested excluding or modifying the measure.

Response: Tobacco use is harmful to patient health, but among diabetics, it is particularly dangerous as it increases the risk of complications. To substantially lower the risk for cardiovascular and stroke events among patients with diabetes, it is critical that the specified outcome goals are achieved. This quality measure aims to encourage even greater engagement by physicians and their diabetic patients in achieving tobacco free status. Although we are not finalizing this individual measure, it is part of the diabetes composite under proposed measure 35 that we are finalizing in this rule. At the time the proposed rule was published,

[4] *American Diabetes Association. Standards of Medical Care in Diabetes—2011. Available at http://care.diabetesjournals.org/content/34/Supplement_1/S11.full.*

some aspects of the measure had not yet received NQF endorsement. Since the measure has now been endorsed as part of the Optimal Diabetes Care composite (NQF #0729), we can clarify that this has now been changed to a different NQF measure, ''Tobacco Non-Use.'' This measure is specifically endorsed for use in diabetics, whereas the measure proposed (NQF #28) is a general preventive health measure we would have calculated for a diabetic population. We recognize concerns for gaming and intend to use the GPRO audit and validation process described in section II.F.4.b. of this final rule, to monitor such activities.

Comment: Proposed measure 40. Diabetes Mellitus: Hemoglobin A1c Poor Control. One commenter questioned inclusion of this measure stating it was not evidence-based, citing research suggesting that interventions to maintain glycemic control in the frail elderly may adversely affect outcomes. One commenter recommended CMS remove this measure as it is not aligned with patient goals.

Response: We are finalizing this measure as we believe glycemic control is an important quality issue. The American Geriatrics Society guidelines currently state that avoiding poor glycemic control is important even for frail older adults; therefore, we believe this measure is consistent with the standard of care and aligned with patient goals.[5]

Comment: Proposed measure 41. Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus. One commenter stated that this measure is not geared towards population health and should be removed.

Response: We included this measure as a population health measure because diabetes is prevalent in the Medicare population and has high rates of morbidity and mortality. Most people with diabetes have other risk factors, such as high blood pressure, that increase the risk for heart disease and stroke. However, we are not finalizing this as an individual measure, because it is part of the diabetes composite, proposed measure 35. that we are finalizing.

Comment: Proposed measures 42.–44. At Risk Population—Diabetes. One commenter supported including proposed measure 42. Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients. Another commenter believed this measure could be removed as it only measured process. One commenter stated that, regarding proposed measure 43. Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients, there are alternatives to dilated eye exams and recommended providers not be penalized for using those alternatives. We did not receive any comments on proposed measure 44. Diabetes Mellitus: Foot Exam.

Response: We are not finalizing these measures at this time. While we agree that nephropathy screening, eye exams, and foot exams are important for diabetics, in order to reduce the burden of the quality reporting at the start of the Shared Savings Program, we have sought to include only the most high impact diabetes intermediate outcome measures and are not finalizing these measures at this time. If the commenter that recommended eye exam alternatives is referring to fundus photographs as the alternative, the 2011 American Diabetes Association (ADA) Standards of Medical Care in Diabetes still recommend dilated eye exams and state that while retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam.

Comment: Proposed measures 45–51. At Risk Population—Heart Failure. One commenter supported proposed measures 45. Heart Failure: Left Ventricular Function (LVF) Assessment and 46. Heart Failure: Left Ventricular Function (LVF) Testing. A few of commenters stated that LVF assessment reflects a minimal standard of care and urged CMS to go beyond structure and process measures to measures that solidly address clinical appropriateness and overuse. Another commenter questioned how meaningful these measures are as they may already have high performance levels and, therefore, have little room for additional quality improvement. Another commenter wrote in support of proposed measure 49. Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).

One commenter was concerned that proposed measure 47. Heart Failure: Weight Measurement was duplicative to proposed measure 31 (Adult Weight Screening and Follow-up). One commenter stated that the measure developer had retired this measure. Another commenter stated the measure was of limited value because it fails to differentiate between providers.

One commenter stated proposed measure 48. Heart Failure: Patient Education was of limited value because it fails to differentiate between providers. Another commenter wrote in support of proposed measure 50. Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction, while another commenter questioned the value of this measure as it already has high performance levels in some regions.

One commenter wrote in support of proposed measure 51. Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation. Another commenter noted that this measure is outdated and should be modified to include thrombin inhibitor therapy, and one commenter recommended removing this measure entirely.

Response: While we agree that LVF testing has improved, 2011 AMA–PCPI guidelines cite LVF assessment, Patient Education, and ACEI/ARB Therapy for LVSD as opportunities for improvement. (*http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/hfset-12-5.pdf*) However, in response to comments about reducing the number of quality measures and in an effort to finalize higher impact measures, we are not finalizing LVF assessment (proposed measure 45), LVF testing (proposed measure 46), Patient Education (proposed measure 48), or ACEI/ARB Therapy for LVSD (proposed measure 50). We are also not finalizing the Heart Failure: Weight Measurement measure (proposed measure 47), as it is retired, as one commenter noted. We are also not finalizing the Warfarin Therapy measure (proposed measure 51) but intend to further research the implications of such a measure of warfarin therapy as opposed to one of thrombin inhibitor therapy and revisit this in the future.

Of the measures proposed for heart failure, we believe there is greatest opportunity for quality improvement in the Beta-Blocker Therapy for LVSD (proposed measure 49) and ACSC: Congestive Heart Failure (proposed measure 15), aimed at reducing avoidable admissions, and are finalizing both measures.

Comment: Proposed measure 52. Coronary Artery Disease (CAD) Composite: All or Nothing Scoring. Comments discussed previously with proposed measure 35.

Response: We have finalized this measure with modification to include only the following components: Drug Therapy for Lowering LDL-Cholesterol and Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction

[5] Guidelines for Improving the Care of the Older Person with Diabetes Mellitus. California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with Diabetes. American Geriatrics Society. May 2003—Vol. 51, No. 5 Supplement, JAGS.

(LVSD). Since CAD is a common chronic condition and is an underlying condition for individuals with other chronic conditions, we are narrowing our composite measure to focus on CAD measures that better align with final measures in other chronic disease areas. In addition, while we will score this measure as a composite measure, we will provide feedback on the individual components so ACOs can identify areas of lower performance and design strategies to improve performance.

Comment: Proposed measure 53. Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD. One commenter wrote in support of this measure.

Response: We are not finalizing this measure at this time, as we believe the aspirin use component of the diabetes composite (proposed measure 35) and the IVD: Use of Aspirin or Another Antithrombotic measure (discussed under proposed measure 39) align and complement the CAD measures given the overlap in the chronic disease population. Therefore, we are finalizing the diabetes composite and the IVD: Use of Aspirin or Another Antithrombotic measures in lieu of proposed measures 39 and 53.

Comment: Proposed measure 54. Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL–Cholesterol. One commenter wrote in support of this measure. One commenter suggested dropping this measure and retaining proposed measure 56 (Coronary Artery Disease: LDL Level <100 mg/dl) in order to pare down measures and retain those with the most impact on health outcomes. Another commenter questioned whether there is demonstrated variability on this measure and whether it was of value.

Response: We note that AMA–PCPI identified this measure as an opportunity for improvement and as a result have retained the measure in the final measure set under the CAD composite (proposed measure 52) but not as an individual measure, since we believe CAD is an area in which we can raise the bar for quality improvement through all or nothing scoring.

Comment: Proposed measure 55. Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI). One commenter wrote in support of this measure. Another commenter cautioned CMS to use the most recent version of this measure, which was updated to include patients with left ventricular systolic dysfunction. One commenter expressed concern about the sample size for most ACOs, whether there is demonstrated variability in the measure, and exclusions for patients who have contraindications to beta blockers.

Response: We have taken the measure update into consideration and decided not to finalize the measure at this time as we believe the IVD measure we are finalizing (discussed under proposed measure 39) is a broader measure that encompasses this aspect of CAD care and allows us to reduce reporting burden to ACOs by requiring fewer measures to be reported.

Comment: Proposed measure 57. Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Dysfunction (LVSD). One commenter questioned whether there is demonstrated variability in this measure and whether allowances would be made for patients with contraindications to ACEs/ARBs.

Response: We believe this measure has room for improvement and have decided to finalize this measure under proposed measure 52, the CAD composite measure, rather than as an individual measure, as we believe CAD is an area in which we can raise the bar for quality improvement through all or nothing scoring. We will take contraindications into account prior to releasing measures specifications.

Comment: Proposed measure 58. Hypertension: Blood Pressure Control. One commenter stated that this measure is dependent on medical record data making it particularly difficult for ACOs to collect and report and recommended it not be included, at least initially. One commenter stated that this measure is not geared towards population health and should be removed. One commenter believed beneficiary compliance to be outside the provider's control and recommended that CMS monitor this measure rather than include it in the performance score.

Response: Many of these measures are based on medical record data and will be collected through the GPRO web interface, which will allow data collection from electronic medical records, patient registries and other administrative systems, as well as from paper records. Hypertension is one of the most common chronic illnesses in the Medicare population and a major cause of morbidity and mortality and a contributing risk factor for other highly prevalent conditions such as diabetes and heart disease. Although some factors influencing outcome measures are outside the provider's control, many others, such as tailoring blood pressure medications and nutrition education, can be influenced by services received through the ACO. Therefore, we are finalizing this measure in the final set.

Comment: Proposed measure 59. Hypertension: Plan of Care. Several commenters recommended removing this measure. Their reasons included: Concerns that the measure is not geared towards population health; it is inefficient; labor intensive; and not scalable. Another commenter believed this measure could be removed as long as Hypertension: Blood Pressure Control was retained.

Response: We believe this measure is important, but may have some overlap with the Adult Weight Screening and Follow-up measure (proposed measure 31), which also includes a plan of care component. Thus, we are not finalizing this measure in an effort to be sensitive to general measures comments about the number of required measures and redundancy. We are, however, retaining the Hypertension: Blood Pressure Control measure, consistent with one commenter's suggestion.

Comment: Proposed measure 60. Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation. One commenter wrote in support of retaining this measure. One commenter recommended CMS use age limits for this measure.

Response: We are not finalizing the measure at this time, in an effort to respond to general comments about the number of required measures and reporting burden. If the commenter that recommended the use of age limits for this measure is suggesting changes to the endorsed specification, we recommend communicating with the measure steward directly. We note, however, that we are finalizing the ACSC: COPD measure (proposed measure 14) as previously discussed.

Comment: Proposed measure 61. Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received. One commenter wrote in support of retaining this measure. One commenter expressed concern that this measure could be gamed and suggested excluding or modifying the measure.

Response: Tobacco use is harmful to patient health, but among patients with COPD, it is particularly harmful as it can cause progression of the illness. We acknowledge the potential for gaming, which is why we proposed a GPRO audit and validation process. However, we have decided not to finalize this measure at this time, as we believe smoking cessation counseling is important for all patients. Accordingly, we are instead finalizing the Tobacco Use Assessment and Tobacco Cessation Intervention measure (proposed measure 33), which includes

individuals with COPD. We believe this decision is also responsive to general comments about the number of required measures, redundancy in the measures, and reporting burden.

Comment: Proposed measure 62. Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy based on FEV1. Two commenters wrote in support of this measure.

Response: We are not finalizing this measure at this time, but we are finalizing the ACSC: COPD measure (proposed measure 14), which aims to reduce avoidable admissions and is outcome focused.

Comment: Proposed measure 63. Falls: Screening for Fall Risk. Several commenters supported this measure. One commenter stated that this is a survey-based measure and should not be submitted via GPRO but could be added to CG CAHPS. This commenter also noted that the proposed measure does not match the current measure description in the 2011 NCQA HEDIS Specifications Volume II.

Response: We believe it is important for an ACO to conduct a fall risk screening or have one noted in a patient's medical record and to report this measure. The CG CAHPS is a patient-reported survey, which we do not think is appropriate for this measure, given the required involvement of a provider educated about requirements for a meaningful assessment. We are finalizing this measure and have adjusted the measure description in Table 1 to reflect the NQF description. We agree that the proposed measure does not match the 2011 HEDIS measure description, but HEDIS includes a different measure (NQF #35) than the one proposed for ACO (NQF #101). We are also moving this measure to the Care Coordination/Patient Safety domain as we believe it is more accurately characterized as a patient safety measure.

Comment: Proposed measure 64. Osteoporosis Management in Women who had a Fracture. Two commenters wrote in support of this measure. One commenter commended CMS for inclusion of this measure but recommended that it be expanded to include men who have had a fracture based on recent literature. One commenter believed that CMS should align ACO and PQRS measures by replacing this measure with the four NQF-endorsed osteoporosis measures in PQRS.

Response: At this time, we have decided not to finalize this measure in order to allow ACOs to focus their efforts to redesign their care processes to incorporate fall risk assessments and to use those results in meaningful conversations with their patients about fall risks and ways to reduce them. As ACOs gain more experience in integrating the fall risk screening measure more broadly into their day-to-day practices, we will revisit the frail elderly measures in future rulemaking to build upon these achievements and to address additional issues for the frail elderly.

Comment: Proposed measure 65. Monthly INR for Beneficiaries on Warfarin. One commenter wrote in support of this measure. One commenter suggested CMS use ACOVE guidelines for INR. One commenter suggested CMS modify its proposal to measure the quality of warfarin therapy by measuring patients on stabilized warfarin therapy within the critical INR range. Several commenters recommended removing of this measure and believed it was out of date.

Response: We have decided not to finalize the measure at this time. We intend to investigate the appropriateness of warfarin therapy further, including developments regarding of alternative therapies and gaps in monthly INR monitoring, and will consider this measure and/or other related measures that may be appropriate in future rulemaking cycles.

Comment: While a majority of commenters suggested paring down the measure set, we received a number of suggestions for additional measures and measure categories that were not included in our proposed measures set, such as measures of: emergency room visits, comprehensive medication management, patient safety, additional potentially preventable complications, care transitions, more robust mental health measures, substance use, underuse of health care services, perioperative care, cancer survivorship care, hematology care, kidney disease, COPD, asthma and other allergic diseases, patient engagement, recovery and wellness. Several commenters recommended including risk-adjusted mortality measures for the entire ACO population, not limited to those who have been hospitalized. A few commenters advocated for more emphasis on continued quality improvement rather than quality assurance.

Response: Given that many ACOs will be newly forming organizations, we concluded that ACO quality measures should focus on discrete processes and short-term measurable outcomes derived from administrative claims and limited medical record review facilitated by a CMS-provided web interface to lessen the burden of reporting. For both the proposed rule and this final rule, we selected a set of quality measures based on the criteria discussed in section II.F.2.b. of this final rule. Because of the focus on Medicare FFS beneficiaries, our measure selection emphasized prevention and management of chronic diseases that have high impact on these beneficiaries such as heart disease, diabetes mellitus and chronic obstructive pulmonary disease.

Comment: A number of commenters were concerned that the program measure quality across the spectrum of care settings including not just outpatient clinics and short-term acute hospital care but also federally qualified health centers, rural environments, convenient care clinics, home health, telehealth, remote patient monitoring, SNFs or long-term care, behavioral health, rehabilitation care, anesthesia care, hospice and palliative care, and case management. A number of these commenters suggested adding specific measures. One commenter advocated for a separate domain of palliative care.

Response: We selected final measures with a predominantly ambulatory care focus, consistent with the primary care focus of, and beneficiary assignment methodology used for, the Shared Savings Program. It is important to note, however, that ACOs may use information from additional care settings types of providers in reporting quality information via the GPRO web interface and that patients' total Medicare Part A and B claims history will be used in determining GPRO measure denominators and calculating claims-based measures. We encourage ACOs to work with providers across the care spectrum to better coordinate care and improve the quality of care for their mutual patient population.

Comment: A number of commenters suggested that new measures are needed for ACOs and that CMS should partner with others, such as Regional Health Improvement Collaboratives and AHRQ, to identify gaps and develop new measures. One commenter supported development of new patient-centered functional outcome measures that are site-neutral, focused on the coordination of services, and based on individual needs and preferences for care. Another stated that new measures specific to the ACO patient experience should be developed in the future but not prior to the launch of the ACO program. One commenter recommended development of measures of appropriate use of new technologies. One commenter expressed concern that current measures reflect limitations of the current payment system, while ACO metrics should

include population-based outcomes measures such as emergency room use, potentially preventable admission rates, in-hospital mortality rates, and possibly patient safety measures. One commenter supported measures of how ACO professionals use their performance on quality measures to improve care as well as the quality measures themselves. One commenter proposed that emergency medicine measures should be developed, while another urged CMS to work with NQF to develop more robust measures of medication management.

Response: We appreciate the commenters' interest in measures that address additional areas of specialty care, inpatient and post acute care while working to move our measurement strategy to more outcome-oriented measures and will consider these in the future.

Comment: A number of commenters recommended CMS include measures that are more inclusive of specialty care, pediatric care, and non-physician professionals, such as nurse practitioners and registered nurses. Many of these commenters noted that the proposed measures were heavily focused on primary care. One commenter believed the emphasis on primary care measures would result in much less data on which to judge ACO quality for specialty care, which could either inappropriately reward or punish specialist providers. Other commenters expressed concern that specialty care and care for those with disabilities might be negatively affected by the lack of specialty measures or incentives to skimp on necessary care. One commenter added that most proposed measures have no direct relationship to cost management that could be achieved during the ACO agreement period, particularly since specialty care is a driver of cost differences. Without specific quality measures related to specialty care, the commenter argues, specialists in ACOs will face pressure to reduce the costs of specialty care, which may translate into inferior care for beneficiaries by limiting access to specialty care and ignoring quality. Several commenters recommended measures that reflect the interprofessional nature of an ACO and the mix of clinicians providing primary care.

Response: We believe that the final set of measures is appropriately focused and measures care furnished by a variety of providers including specialists, nurses, and nurse practitioners. We also believe the issue of including specialty providers who furnish primary care services is addressed in the two-step beneficiary assignment methodology discussed in section II.E of this final rule. We also agree that monitoring is necessary to ensure providers do not skimp on care or avoid at-risk beneficiaries. Our final policies regarding monitoring of ACOs are discussed in section II.H. of this final rule. Finally, we do not think including pediatric measures is appropriate at this time, since the Shared Savings Program is designed for the Medicare FFS population, which includes very few children and would not allow for reliable and valid pediatric measures.

We also received suggestions for a process to retire and add measures over time.

Comment: A few commenters recommended CMS take steps to assure that the most recent version of a specification, per the measure developer, is being used and that measures keep pace with current evidence. One commenter suggested that we conduct an annual review of the quality measures as well as new scientific evidence published in peer-reviewed medical literature and comparative effectiveness research of the Patient-Centered Outcomes Research Institute (PCORI) and remove any measures that are no longer supported by the evidence. Another commenter suggested that CMS should plan to update evaluation tools and methods as advances allow. One commenter requested that CMS assure that quality measures keep pace with new technologies and advances in medical care. Another commenter recommended CMS specify its criteria for selecting future measures and suggested beginning with: correlation with outcomes; NQF endorsement; measure impact (that is, high-volume, high-cost); sufficient sample size; existence of complete and clear specifications; compound or composite measures; and degree of opportunity for improvement, as indicated by high variability across organizations. One commenter stated that measures should be meaningful to consumers.

A few commenters suggested that measures not be modified or added during the first agreement period or, at minimum, that we institute a system similar to the final value-based purchasing system where measures must be reported for a year without specification changes before they are eligible to be added to the performance standard. These commenters stated that keeping measures constant would allow ACOs to compare results from year to year. One of these commenters thought, at a minimum, any new measures added during an agreement period should be reasonable in number and limited to those that have been publicly reported for one year, in line with the HVBP model. One commenter requested CMS clarify how ACOs will be notified of changes to quality reporting in subsequent years and how new quality measures would be vetted. Another commenter recommended measures be added through an approval process open to all interdisciplinary health providers through their professional organizations while another commenter recommended that CMS use a formal notice and comment process to retire or add measures so that all stakeholders have the opportunity for input. One commenter suggested CMS add new measures during the agreement period for reporting only and not include those in the shared savings calculation. This commenter also recommended that more than 90 days lead time should be given before new measures are added. A few commenters recommended publishing final measure specifications at least 90 days in advance for 2012 and at least 180 days notice be given for subsequent years, while another commenter recommended that CMS publish sample approach, sample size and data collection rules for any survey tools at least 12 months in advance. Another commenter recommended measures be published at least 18 months in advance. One commenter suggested that measures which are substantially modified be reported for a year prior to being incorporated into the performance standard. One commenter suggested measures be added only if they meet an ACO's patient population needs and removed if they are found to be unreliable, unactionable, or do not meet the needs of the population served.

Response: As discussed previously, detailed measure specifications, including the measure title, for the Shared Savings Program quality measures may have been updated or modified during the NQF endorsement process or for other reasons prior to 2012. Specifications for all Shared Savings Program quality measures must be obtained from the specifications document for Shared Savings Program quality measures. As measures stewards frequently make their measures updates for a given year during the 4th quarter of the preceding year or the 1st quarter of the applicable year, we expect to release specifications during the 4th quarter of 2011 or the 1st quarter of 2012 for most of the measures. We expect to release specifications for the CAHPS survey later in 2012. We will also add and retire measures as

appropriate through the rulemaking process. We are working with the measures community to ensure that our specifications are the most up-to-date for the 2012 Shared Savings Program performance period. We have to balance timing the release of specifications so they are as up-to-date as possible, while also giving ACOs sufficient time to review specifications.

Comment: One commenter requested that CMS clarify exclusion options for situations when following an evidence-based guideline would be inappropriate for a given ACO patient. A few commenters noted many of the proposed measures are inappropriate for terminally ill patients and recommended excluding such patients from quality measure calculations without consequence to the ACO.

Response: Measure owners identify appropriate exclusion criteria as part of their measure specifications. Additionally, measures collected via the GPRO web interface allow providers to exclude patients per the measure specifications and for other defined reasons related to the reporting methodology as appropriate. The ACO measures specifications and reporting methodology will be provided in subregulatory guidance. However, in the proposed rule, we included information, such as the NQF number, for each measure so that the public could view measures specifications information on the NQF Web site and as currently used in other CMS programs, such as PQRS and the EHR Incentive Programs. Our audit and validation process and monitoring activities will also look at exclusions to determine if ACOs are excluding large numbers of patients from quality reporting as a way to avoid reporting or to game the methodology.

Comment: Many commenters suggested that CMS outline quality reporting requirements over the entire ACO agreement period since Medicare ACOs are required to commit to participating for at least 3 years. One commenter was disappointed that we only aligned with PQRS measures for the first year of the agreement period. One commenter recommended a 2 year reporting-only period for any future new measures that are not currently being collected. One commenter suggested that if measures for the agreement period are not specified up front, an ACO should be able to withdraw from its agreement if the second and third year measure reporting requirements are too burdensome and resource intensive. One commenter urged CMS to specify the reporting period, due date of submission, and the population that is being measured for each of the quality measures in the final rule. One commenter recommended that ACOs not be required to develop clinical guidelines and instead we should encourage them to use those developed by medical specialty societies. There was widespread support among commenters for a ramp-up approach to measurement and linking the degree of measure reporting—or in later years, measure performance—to the degree of shared savings. Many commenters believed phasing in measures or having a tiered approach, rather than requiring ACOs meet all thresholds would encourage wider participation, allow ACOs time to develop the necessary infrastructure and capacity, and reduce startup costs. Several commenters proposed a tiered approach to the performance standard. A few commenters stated that this approach would not only encourage participation but would help avoid some of the learning curve issues that occur in new programs. Several commenters pointed to the approach taken by the PGP Demonstration, in which an initial set of measures was phased in over time, and suggested the Shared Savings Program take a similar approach.

While a number of commenters endorsed the first year quality performance standard at the reporting level, a number of commenters recommended extending it for 2 years, and a few endorsed a pay-for-reporting standard for the entire first agreement period. Another commenter requested that, if measures which are not in current use are included in the final rule, these be kept at the reporting standard for the entire agreement period. One commenter thought the proposed Ambulatory Care Sensitive Conditions and Risk Standardized All Condition Readmission measures proposed should be pay for reporting measures only during the entire agreement period, due to the associated cost and risk, similar to the way in which new measures have been treated under the PGP demonstration. One commenter urged CMS not to use the reporting standard and to establish at least a minimum performance threshold from the outset of the program.

Response: We have outlined in Tables 1 and 2 the quality measure requirements for the ACO agreement period. We do not intend to develop specific clinical guidelines for ACOs. Rather, we intend to adopt existing clinical guidelines as appropriate for ACOs in our measure specifications. Withdrawal from the Shared Savings Program is discussed in section II.H.5. of this final rule. A subset of these measures will be phased in for performance scoring starting in performance year 2 of the agreement period, as illustrated in Table 1 and summarized in Table 2. We believe this approach emphasizes all domains and measures as important, provides a longer phase in of measures to pay for performance than in our original proposal, and aligns closely with the phase in used in the PGP Transition Demonstration.

We expect to require ACOs to report all measures listed in Table 11 during each ''reporting period,'' as defined in § 425.20, of its agreement. This means that while an ACO's first ''performance year,'' as defined in § 425.20, for shared savings purposes would be 18 or 21 months, quality data will be collected on a calendar year reporting period basis, beginning with the reporting period starting January 1, 2012 through December 31, 2012 for ACOs electing an interim payment. Thus, the first performance year of the ACO agreement period begins April 1, 2012 or July 1, 2012 and ends December 31, 2013, while quality performance for this first performance year will be based on complete and accurate reporting of measures January 1, 2013 through December 31, 2013. Quality data submitted via the GPRO web interface for the 2012 reporting period would also be used for purposes of the PQRS incentive under the Shared Savings Program, as discussed in II.F.5. of this final rule and for the interim payment calculation, as discussed in II.G.2.k. of this final rule. Furthermore, for all ACOs starting in 2012, we will conduct a CAHPS survey with assigned ACO beneficiaries and will measure claims- and administrative-based quality measures. Complete and accurate reporting on all quality measures in Table 1 for both the calendar year 2013 will be used to determine shared savings eligibility for an ACO's first performance year. The pay for performance phase-in of measures and second performance year for shared savings purposes would begin January 1, 2014. Table 2 summarizes the number pay for reporting and pay for performance measures for each performance year.

TABLE 1—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS

	Domain	Measure title	NQF measure #/measure steward	Method of data submission	Pay for performance phase in R = Reporting P = Performance		
					Year 1	Year 2	Year 3
AIM: Better Care for Individuals							
1.	Patient/Caregiver Experience.	CAHPS: Getting Timely Care, Appointments, and Information.	NQF #5, AHRQ.	Survey	R	P	P
2.	Patient/Caregiver Experience.	CAHPS: How Well Your Doctors Communicate.	NQF #5 AHRQ.	Survey	R	P	P
3.	Patient/Caregiver Experience.	CAHPS: Patients' Rating of Doctor.	NQF #5 AHRQ.	Survey	R	P	P
4.	Patient/Caregiver Experience.	CAHPS: Access to Specialists.	NQF #5 AHRQ.	Survey	R	P	P
5.	Patient/Caregiver Experience.	CAHPS: Health Promotion and Education.	NQF #5 AHRQ.	Survey	R	P	P
6.	Patient/Caregiver Experience.	CAHPS: Shared Decision Making.	NQF #5 AHRQ.	Survey	R	P	P
7.	Patient/Caregiver Experience.	CAHPS: Health Status/ Functional Status.	NQF #6 AHRQ.	Survey	R	R	R
8.	Care Coordination/Patient Safety.	Risk-Standardized, All Condition Readmission*.	NQF #TBD CMS.	Claims	R	R	P
9.	Care Coordination/Patient Safety.	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease (AHRQ Prevention Quality Indicator (PQI) #5).	NQF #275 AHRQ.	Claims	R	P	P
10.	Care Coordination/Patient Safety.	Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8).	NQF #277 AHRQ.	Claims	R	P	P
11.	Care Coordination/Patient Safety.	Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment.	CMS	EHR Incentive Program Reporting.	R	P	P
12.	Care Coordination/Patient Safety.	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.	NQF #97 AMA–PCPI/ NCQA.	GPRO Web Interface.	R	P	P
13.	Care Coordination/Patient Safety.	Falls: Screening for Fall Risk.	NQF #101 NCQA.	GPRO Web Interface.	R	P	P
AIM: Better Health for Populations							
14.	Preventive Health	Influenza Immunization	NQF #41 AMA–PCPI.	GPRO Web Interface.	R	P	P
15.	Preventive Health	Pneumococcal Vaccination	NQF #43 NCQA.	GPRO Web Interface.	R	P	P
16.	Preventive Health	Adult Weight Screening and Follow-up.	NQF #421 CMS.	GPRO Web Interface.	R	P	P
17.	Preventive Health	Tobacco Use Assessment and Tobacco Cessation Intervention.	NQF #28 AMA–PCPI.	GPRO Web Interface.	R	P	P
18.	Preventive Health	Depression Screening	NQF #418 CMS.	GPRO Web Interface.	R	P	P
19.	Preventive Health	Colorectal Cancer Screening.	NQF #34 NCQA.	GPRO Web Interface.	R	R	P
20.	Preventive Health	Mammography Screening	NQF #31 NCQA.	GPRO Web Interface.	R	R	P
21.	Preventive Health	Proportion of Adults 18+ who had their Blood Pressure Measured within the preceding 2 years.	CMS	GPRO Web Interface.	R	R	P
22.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (<8 percent).	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P

TABLE 1—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

	Domain	Measure title	NQF measure #/measure steward	Method of data submission	Pay for performance phase in R = Reporting P = Performance		
					Year 1	Year 2	Year 3
23.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (<100).	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
24.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Blood Pressure <140/90.	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
25.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Tobacco Non Use.	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
26.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Aspirin Use.	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
27.	At Risk Population—Diabetes.	Diabetes Mellitus: Hemoglobin A1c Poor Control (>9 percent).	NQF #59 NCQA.	GPRO Web Interface.	R	P	P
28.	At Risk Population—Hypertension.	Hypertension (HTN): Blood Pressure Control.	NQF #18 NCQA.	GPRO Web Interface.	R	P	P
29.	At Risk Population—Ischemic Vascular Disease.	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/dl.	NQF #75 NCQA.	GPRO Web Interface.	R	P	P
30.	At Risk Population—Ischemic Vascular Disease.	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.	NQF #68 NCQA.	GPRO Web Interface.	R	P	P
31.	At Risk Population—Heart Failure.	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	NQF #83 AMA–PCPI.	GPRO Web Interface.	R	R	P
32.	At Risk Population—Coronary Artery Disease.	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Drug Therapy for Lowering LDL-Cholesterol.	NQF #74 CMS (composite)/ AMA–PCPI (individual component).	GPRO Web Interface.	R	R	P
33.	At Risk Population—Coronary Artery Disease.	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD).	NQF #66 CMS (composite)/ AMA–PCPI (individual component).	GPRO Web Interface.	R	R	P

*We note that this measure has been under development and that finalization of this measure is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012.

TABLE 2—ACO AGREEMENT PERIOD PAY FOR PERFORMANCE PHASE-IN SUMMARY

	Performance year 1	Performance year 2	Performance year 3
Pay for Performance	0	25	32
Pay for Reporting	33	8	1
Total	33	33	33

Final Decision: In summary, in response to comments, we have modified this final rule by reducing the measure set to 33 measures total, or 23 scored measures when accounting for the patient experience survey modules scored as 1 measure and the all or nothing diabetes and CAD measures scored as 1 measure each. We believe judiciously removing certain redundant, operationally complex, or burdensome measures would still provide a high standard of quality for participating ACOs while providing greater alignment with other CMS and HHS quality improvement initiatives. This measure set will be the starting point for ACO measurement, as we plan to modify measures in future reporting cycles to reflect changes in practice and quality of care improvement and continue aligning with other quality programs.

For the patient/caregiver experience measures, we believe requiring a standardized, patient experience of care survey that is based on CAHPS will better allow comparisons of ACOs over time and benchmarking for future years of the program. Additionally, it will help ensure the patient survey is measuring patient experience for the ACO as a whole rather than for one specific practice, since there is currently no survey instrument in existence, that we are aware of, that measures patient experience of care in an ACO specifically. We will also fund the administration of an annual CAHPS patient experience of care survey for ACOs participating in the Shared Savings Program in 2012 and 2013. Starting in 2014, ACOs participating in the Shared Savings Program must select a survey vendor (from a list of CMS-certified vendors) and will pay that vendor to administer the survey and report results using standardized procedures developed by CMS. We will develop and refine these standardized procedures over the next 18 to 24 months.

We will consider the individual CAHPS modules together as one measure for scoring purposes, consistent with Hospital Value-Based Purchasing and the PGP Transition Demonstration, except for Health Status/Functional Status. We have also added an access to specialists module to align with our final step-wise assignment methodology that incorporates specialists. This module will also promote care coordination and allow monitoring for avoidance of at-risk patients and underutilization of care by adding a patient perspective on access to specialty care. We will score the two finalized coronary artery disease measures as one composite and the recently endorsed Optimal Diabetes Care Composite, which has 5 components, will also be scored as one composite.

ACOs will be required to completely and accurately report on all 33 measures for all reporting periods in each performance year of their agreement period, and we will phase in pay for performance in performance years 2 and 3, as previously described above. Of the 33 measures we are finalizing, 7 are collected via patient survey, 3 are calculated via claims, 1 is calculated from EHR Incentive Program data, and 22 are collected via the GPRO web interface.

While we are removing the hospital patient safety measures from the final measures set, we plan to use the claims-based hospital measures as part of our ACO monitoring efforts. We also intend to consider any other claims-based measures proposed but not finalized in our program monitoring efforts. Please note that detailed measure specifications, including the measure title, for the 2012 Shared Savings Program quality measures may have been updated or modified during the NQF endorsement process or for other reasons prior to 2012. Specifications for all 2012 Shared Savings Program quality measures must be obtained from the specifications document for 2012 Shared Savings Program quality measures, which we expect to make available on the CMS Web during the 4th quarter of 2011 or 1st quarter of 2012, with the exception of the CAHPS measures, for which separate documentation will be available during 2012. We also note that the risk standardized, all condition readmission measure (final measure #2) has been under development and that finalization of this measure is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012.

Finally, we have modified this final rule to define the quality performance standard at the reporting level in the first year and based on performance in subsequent years. Rather than transition all measures from pay for reporting to pay for performance in the second performance year of the ACO agreement period as proposed, we will transition only a portion of the measures to pay for performance in the second performance year, and then all but one of the measures to pay for performance in the third performance year, as outlined in Table 2.

3. Requirements for Quality Measures Data Submission by ACOs

a. General

Under section 1899(b)(3)(B) of the Act, ACOs are required to submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. In the proposed rule, we stated that most of the proposed measures were consistent with those reported for PQRS, others would rely on survey instruments, eRx, and HITECH program data, and some might rely on Hospital Compare or the Centers for Disease Control and Prevention National Healthcare Safety Network data (76 FR 19592). We recognized that there are a number of limitations associated with claims-based reporting, since the claims processing system was designed for billing purposes and not for the submission of quality data. For this reason, we stated we would make available a CMS-specified data collection tool for certain measures, which is now referred to as a ''web interface.'' We proposed that during the year following the first performance period, each ACO would be required to report via the GPRO web interface the applicable proposed quality measures with respect to services furnished during the performance period. We proposed that we would derive the claims-based measures from claims submitted for services furnished during the first performance period, which therefore would not require any additional reporting on the part of ACO professionals. We also proposed that for survey-based measures data would also reflect care received during the first performance period. We also noted that we would use rulemaking to update the quality measure requirements and mechanisms for future performance periods.

We welcomed comments on the proposed data submission requirements. We also sought comment on whether alternative data submission methods should be required or considered, such as limiting the measures to claims-based and survey-based reporting only.

We received the following comments about data submission requirements in general.

Comment: Several commenters requested more complete specifications about data submission requirements in the final rule. A few commenters stated that multiple formats of reporting are expensive and confusing and suggested a single reporting format. One commenter supported the multiple

approaches to capture quality data. A few commenters recommended that CMS require ACOs to measure quality for all patients, not just Medicare beneficiaries. One commenter recommended CMS require ACOs to give ACO providers/suppliers access to claims data arguing that such transparency is needed to ensure that all ACO providers/suppliers understand how their performance rates are being calculated. A few commenters expressed concern about whether CMS has the resources to handle the incoming data. One commenter did not believe ACOs should be held accountable for CMS problems with implementation.

Response: We were as specific as practicable in the proposed rule regarding the data submission requirements. More detailed instructions regarding data submission will be provided through subregulatory guidance. We agree with the commenters' concern about a standard format for reporting purposes to ensure consistent reporting over years and by multiple ACOs. We believe the GPRO web interface provides this mechanism for ACOs to report data at the individual beneficiary level. It was developed with provider input and is currently used in multiple physician pay for performance demonstrations and in the PQRS group practice reporting option. The tool is pre-populated with Medicare claims data for a sample of assigned beneficiaries for each ACO to minimize reporting burden and to ensure complete and accurate reporting. While CMS encourages ACOs to measure quality for all their patients, it is beyond the scope of this regulation to require that they do so for patients other than Medicare beneficiaries. We also embrace the concept of data transparency and availability. While we cannot foresee all possible future implementation issues, we will strive to mitigate any unforeseen issues swiftly and fairly.

We received the following comments about survey-based quality data.

Comment: A few commenters stated that the survey data specifications were not sufficiently detailed. One commenter requested clarification on CAHPS timeframe of the last 12 months and asked whether visits outside of the reporting period may be included. A few commenters requested CMS clarify who would administer the survey, required timing, and sample size, while another questioned whether implementation of this measure was feasible for the first year given that this would be a new activity for most ACOs.

Response: As discussed in section II.F.2. of this final rule, we agree with the concerns that have been raised regarding the initial burden of survey administration and have decided to pay for the administration of the CAHPS survey for 2012 and 2013. We are developing the necessary specifications and infrastructure to prepare vendors to administer the survey. Starting in 2014, ACOs will be required to select and pay for a CMS-approved vendor to administer the survey.

Comment: One commenter requested that the final rule clearly articulate the reporting period, due date of submission, and the population that is being measured for each of the quality measures. One commenter wrote in support of the 12-month performance period as it allows for more valid and reliable measurement than would be possible under a shorter time period. A few commenters stated that 100 percent reporting may not be achievable in year one.

Response: To clarify, all quality measures will have a 12-month, calendar year reporting period, regardless of ACO start date. Quality measures specifications and processes related to all quality measures will be made available in subregulatory guidance along with the specific dates for reporting and submission. Because of the measures and the methodology we are finalizing in this rule, our experience with GPRO measures and reporting methods to date, along with our plans to administer the CAHPS survey for the first 2 years of the program, we believe ACOs can achieve complete and accurate reporting in all years of the agreement period as we phase in pay for performance. CMS survey vendors will have responsibility for measuring the patient experience measures, and CMS will be able to calculate the claims-based measures and EHR Incentive Program measure without requiring any additional ACO reporting. ACOs will be directly responsible for reporting measures collected through the GPRO web interface. Starting in 2014, ACOs will also be responsible for selecting and paying for a CMS-certified vendor to administer the CAHPS survey.

Comment: Numerous commenters suggested a core and menu set approach to quality measurement, which would require all ACOs to report on a core measure set but allow flexibility to choose among measures in a menu set, similar to that used for the EHR incentive program. Different suggestions as to how to select core measures were received. One commenter suggested a performance score during the first year for a limited set of 11 core measures available through claims data in order to immediately focus on quality performance. Another commenter suggested separating the measures as core, interim clinical process, and advanced sets, with ''core'' referring to administrative claims and patient survey measures and ''advanced'' referring to more advanced, outcomes measures. Advanced measures would be those requiring clinical data such as the proposed preventive health screening measures. One commenter suggested requiring a core set of measures but offering higher shared savings for successful implementation of additional voluntary measures. One commenter suggested reducing the number of measures in each domain to three; another advocated reducing the number within patient/caregiver experience, care coordination, patient safety and preventive health domains to an initial core similar to EHR Incentive Program and emphasized that measures for specific clinical areas should eventually include measures in several domains in as well as for at-risk populations and the frail elderly. This commenter also suggested CMS begin to identify measures for each clinical area within those domains.

Response: We agree with the basic suggestions of a more limited measure set with some type of phased in approach. Table 2 illustrates the desire to have a phased in approach and a smaller, core set of measures that aligns with quality improvement priorities and value-based purchasing, in response to comments received. We do not agree that arbitrarily requiring all domains to have the same number of measures would be beneficial. Rather, we have reduced the number of initial measures, independent of domain, based on feasibility, impact, program goals, and specific comments. At this time, we believe it is important all ACOs report on the same measures in order to emphasize quality improvement across a variety of important areas. We believe that a menu approach would provide incentives for ACOs to select areas in which they are already performing well, rather than those areas in which there is room for improvement.

We received the following comments about claims-based quality measure data.

Comment: Several commenters stated measures should be derived from claims data when possible for ease of reporting and to give ACOs real-time feedback of results. One commenter stated that using existing data for most measures would also be advantageous in that ACOs could be more focused on quality improvement from the outset rather than having to spend resources simply

to track and report quality measures. One of these commenters recommended that measures with HEDIS claims specifications should be collected in that manner. Several commenters recommended beginning with a measure set based on claims data and expanding to registry or EHR-based measures over time. Another commenter indicated that Medicare claims data would yield a limited set of measures and that CMS should instead focus on requiring ACOs to demonstrate core capabilities critical to improving quality and reducing costs. This commenter suggested different levels of scoring similar to NCQA's proposed criteria. One commenter suggested CMS consider, in the future, ABIM's Comprehensive Care Practice Improvement Module, which is designed to assess generalist practice.

Response: We have included measures collected from a variety of sources, including claims, in the final measures set. We recognize that using claims offers a benefit in easing reporting burden but claims do not necessarily reflect the improvement outcomes that ACOs will seek to affect. We also recognize that the availability of measures from electronic health records may change significantly in the future, which we will consider accordingly. We are unable to add new measures in this final rule that were not proposed or that are not closely related to proposed measures. Accordingly, we are finalizing a combination of both claims-based measures and other measures collected from clinical quality data, patient experience surveys, and EHR Incentive Program data.

b. GPRO Web Interface

In 2010, 36 large group practices and integrated delivery systems used GPRO to report 26 quality measures for an assigned patient population under the PQRS. As we indicated in the proposed rule, the GPRO web interface affords a key advantage in that it is a mechanism through which beneficiary laboratory results and other measures requiring clinical information can be reported to us. The web interface would allow ACOs to submit clinical information from EHRs, registries, and administrative data sources required for measurement reporting. We believe the web interface would reduce the administrative burden on health care providers participating in ACOs by allowing them to tap into their existing Information Technology (IT) tools that support data collection and health care provider feedback, including at the point of care. Accordingly, we proposed that the existing GPRO web interface would be built out, refined, and upgraded to support clinical data collection and measurement reporting and feedback to ACOs participating in the Shared Savings Program.

For quality measures collected via the GPRO web interface, we proposed to determine a sample for each domain or measure set within the domain using a sampling methodology modeled after the methodology currently used in the 2011 PQRS GPRO I, as described in section II.F.3.b of the proposed rule. Assigned beneficiaries, for purposes of the GPRO web interface, would be limited to those Medicare FFS beneficiaries assigned to the ACO.

We indicated in the proposed rule that we would provide each ACO with access to the GPRO web interface that would include a sample of its assigned beneficiary population and the GPRO quality measures listed in Table 1 of the proposed rule (76 FR 19592). We stated we would pre-populate the web interface with the beneficiaries' demographic and utilization information based on their Medicare claims data. The ACO would be required to populate the remaining data fields necessary for capturing quality measure information on each of the beneficiaries as applicable.

Using the same sampling method used in the 2011 PQRS GPRO I, we would require that the random sample for measures reported via ACO GPRO must consist of at least 411 assigned beneficiaries per measure set/domain. If the pool of eligible, GPRO assigned beneficiaries is less than 411 for any measure set/domain, then we proposed to require the ACO to report on 100 percent, or all, of the assigned beneficiaries. For each measure set/domain within the GPRO web interface, the ACO would report information on the assigned beneficiaries in the order in which they appear consecutively in the ACO's sample.

We stated that some GPRO measures would not rely on beneficiary data but rather on ACO attestation. We proposed to validate GPRO attestation for such measures through CMS data from the EHR Incentive Program and Electronic Prescribing (eRx) Incentive Program. For the other measures reported via the GPRO web interface, we proposed to retain the right to validate the data entered by ACOs via a data validation process based on the one used in phase I of the PGP demonstration. In the GPRO audit process, we would abstract a random sample of 30 beneficiaries previously abstracted for each of the quality measure domains/measure sets. The audit process would include up to three phases, depending on the results of the first two phases. Although each sample would include 30 beneficiaries per domain, only the first eight beneficiaries' medical records would be audited for mismatches during the first phase of the audit. A mismatch represents a discrepancy between the numerator inclusions or denominator exclusions in the data submitted by the ACO and our determination of their appropriateness based on supporting medical records information submitted by the ACO. If there are no mismatches, the remaining 22 of the 30 beneficiaries' records would not be audited. If there are mismatches, the second phase of the audit would occur, and the other 22 beneficiaries' records would be audited. A third phase would only be undertaken if mismatches are found in more than 10 percent of the medical records in phase two. If a specific error is identified and the audit process goes to Phase 3, which involves corrective action, we proposed to first provide education to the ACO on the correct specification process and provide the opportunity to correct and resubmit the measure(s) in question. If, at the conclusion of the third audit process the mismatch rate is more than 10 percent, we proposed that the ACO would not be given credit for meeting the quality target for any measures for which this mismatch rate still exists. We noted that the failure to report quality measure data accurately, completely and timely (or to timely correct such data) might subject the ACO to termination or other sanctions.

We invited comment on the proposed GPRO quality data submission requirements and on the administrative burden associated with reporting.

Comment: A few commenters supported the use of GPRO although one of the commenters stated that this type of reporting requires considerable time, effort and knowledge to do well and suggested automating measures as much as possible. One commenter encouraged CMS to rapidly develop the GPRO interface for ACOs and requested guidance for data submission in the meantime. One commenter suggested that CMS work with EHR vendors, DIRECT HISPs and HIEs to support efficient interfaces between EHRs, HIE, and the web interface and that the Quality Data Model developed by NQF should be supported to standardize data collection. This commenter also suggested that GPRO should be evaluated for expanded use. However, a few commenters expressed concern about whether GPRO is capable of being expanded for ACO use or its applicability for ACO populations as it has been used primarily for large group practices to date. A few commenters recommended further testing before

using it as proposed. Several commenters did not believe enough information was available about GPRO and baseline metrics from GPRO. One commenter stated that GPRO reported measure specifications are not available for review and interpretation. One commenter requested provider assistance if GPRO reporting is required. Another commenter requested clarification about whether the intent was for GPRO to cover all measures, and whether practices within an ACO would continue to report separately under GPRO for purposes of a PQRS incentive payment. Another commenter recommended that GPRO be populated soon with the prior two years of likely ACO assigned members, including an analysis of claims only results.

Response: We have attempted to weigh the burdens of various reporting mechanisms against the benefits. The original GPRO tool evolved from the PAT tool used for the PGP Demonstration, which was developed with significant physician involvement. Over 600 physicians in a range of practice sizes used it as part of the Medicare Care Management Performance Demonstration, the PQRS had 35 groups using the GPRO tool in 2010 and 61 have signed up for 2011. Additionally, the tool has migrated to a web interface, which will offer the additional capability of data upload from an EHR. As a result, we believe this reporting mechanism is capable and well-tested and represents the best current option for quality reporting. We do not think it would be appropriate or effective to populate the web interface with the prior 2 years of beneficiaries likely to be assigned to an ACO, as one commenter suggested, since this is not the population for which the ACOs will be responsible for being accountable for quality or financial performance. Rather, the ACO will be required to report on the beneficiaries actually assigned to the ACO in 2012. As a result, the web interface will be populated based on a sample of the 2012 assigned beneficiaries. Additionally, the calendar year reporting period for the ACO GPRO quality measures aligns with the PQRS GPRO reporting period for purposes of qualifying ACO TINs for a 2012 PQRS incentive payment, which is discussed in section II.F.5. of this final rule.

We are finalizing our proposal to build upon GPRO experience for ACO use. We have specified in Table 1 which final measures must be reported through the GPRO web interface.

Comment: Several commenters discouraged CMS from using the GPRO web interface because it does not provide a long-term solution to data collection and may hinder development of robust EHR solutions. One commenter encouraged CMS to establish its intent to collect electronic measures in subsequent years of the Shared Savings Program. A number of commenters noted GPRO is a labor intensive reporting method requiring chart abstraction, prone to error, and not derived from the normal workflow of providing patient care and encouraged the use of measures that could be captured by EHRs. One commenter expressed concern about the limited amount of time proposed for data entry in GPRO. Several commenters suggested alternate approaches to reporting. One commenter suggested a parallel reporting pathway via EHR for practices that have invested in health IT. One commenter suggested another standardized option to the GPRO web interface. One commenter recognized that medical record data would result in increased accuracy and recommended CMS prioritize measures for electronic exchange of clinical data between ACOs and CMS in the future rather than introduce the burden associated with the use of the GPRO web interface. Another commenter suggested content analysis of unstructured data available from encounters to more objectively measure some dimensions of quality without increasing reporting burden. This commenter also suggested that content analysis methodology be tested prior to building out the GPRO web interface.

Response: We agree that it is important to foster innovation and support the development and uptake of electronic medical records. For this reason, we are including a measure related to EHR Incentive Program participation in our final measure set. However, we must rely on other means of collecting quality data for the Shared Savings Program until there is much more widespread use of electronic medical records and available means for group reporting based on ACO beneficiary level data. We note that the original GPRO tool evolved from the PAT tool used for the PGP Demonstration, which was developed with significant physician involvement, and over 600 physicians in a range of practice sizes used it as part of the Medicare Care Management Performance Demonstration. PQRS had 35 groups using the GPRO tool in 2010 and currently have 61 signed up for 2011. As a result, we believe this reporting mechanism is sound and well-tested, and we intend to build upon this experience for ACO use. Additionally, the tool has migrated to a web interface, which will offer the additional capability of data upload from an EHR. We do not believe content analysis of unstructured data, as one commenter suggested, would be an efficient or operationally feasible way of collecting and analyzing ACO quality data as it would be difficult and time-consuming to make quality performance standard determinations from non-uniform data. Additionally, the GPRO web interface represents a first step in EHR-based reporting, which we believe is more efficient and cost-effective, since it will allow ACOs to upload data directly from their EHR systems. Meanwhile, those ACOs that would prefer to manually submit data through the GPRO web interface could do so, in a uniform way.

Comment: A few commenters expressed concern about the proposed GPRO data validation process and discussed the difficulty of obtaining medical records across an entire ACO and reconciling those records with quality performance data reported by the ACO. One of these commenters further stated that the data validation process should be tested prior to implementation.

Response: We agree that data validation may be a challenge but do not believe that use of the GPRO web interface significantly adds complexity. Rather, we believe the data validation process implicitly incentivizes ACOs to keep organized and up-to-date medical records and is necessary to protect against the gaming concerns other commenters have noted.

c. Certified EHR Technology

In July 2010, HHS published final rules for the EHR Incentive Programs. The final regulations included certain clinical quality measures on which EPs and eligible hospitals must report as part of demonstrating they are meaningful EHR users. In the proposed rule, we included information on which of the proposed quality measures for the Shared Savings Program are currently included in the EHR Incentive Programs and stated our intent to continue to further align the measures between the two programs. As we intend to further align both the Shared Savings Program and EHR incentive program through subsequent rulemaking, we stated that we anticipated that certified EHR technology (including EHR modules certified to calculate and submit clinical quality measures) would be an additional measure reporting mechanism used by ACOs under the Shared Savings Program in future program years.

Comment: Several commenters supported the use of EHR-derived

measures whenever possible, particularly as the use of EHRs becomes more widespread. One commenter was concerned that EHRs do not currently generate all the data necessary for the proposed performance measures. Others supported the move toward EHR-based measures over time. One commenter was concerned that the proposed measures require providers to have already adopted an EHR. Several commenters suggested special consideration for EHR adoption be given to smaller practices. Several commenters supported movement toward using Health Information Exchange (HIE) as a means of measures reporting. Another commenter expressed concern that the proposed regulations require a level of functional health information exchange that is not yet available, such as a patient online portal to meet the patient-centeredness objective and the need to electronically exchange information with entities outside of the ACO. This commenter suggested that allowing ACOs to determine their own technology needs would result in greater participation and more widespread adoption of best practices. One commenter stated that differences in technology access among providers would inhibit information sharing and care coordination and stated that, if beneficiaries see non-ACO providers, care coordination may be diminished. This commenter requested a separate policy to address care coordination and exchange of information.

Many commenters also recommended that CMS allow data submission through clinical registries and encourage their use as a proven tool to improve quality and control costs and as a way of having real-time actionable data. One commenter also recommended that CMS allow data to be submitted via registry or additional means that have been established by regional collaborative.

Response: While we hope to have more robust capabilities for EHR-derived measures and reporting in the future, at this point we are finalizing one quality measure that rewards and encourages greater EHR use, which is the percent of primary care providers who successfully qualify for an EHR Incentive Program payment. We are also double weighting this measure for scoring purposes as well as for determining poor performing to reflect the importance of HIT for ACOs to redesign care, provide practitioners actionable information at the point of care, and to align incentives and encourage broader EHR adoption. As providers gain more experience with EHR technology, we will reconsider using certified EHR technology as an additional reporting mechanism used by ACOs under the Shared Savings Program.

Final Decision: After considering the comments and for the reasons discussed previously, we are finalizing our proposal to use survey based measures, claims and administrative data based measures, and the GPRO web interface as a means of ACO quality data reporting for certain measures, as listed in Table 1. For the ACO GPRO measures, we are finalizing our proposal to use the same sampling method used in the 2011 PQRS GPRO I, as described previously. We are also finalizing our proposal to retain the right to validate the data ACOs enter into the GPRO web interface via a data validation process based on the one used in phase I of the PGP demonstration, as described previously.

4. Quality Performance Standards

a. General

A calculation of the quality performance standard will indicate whether an ACO has met the quality performance goals that would deem it eligible for shared savings. As discussed previously in section II.F.2. of this final rule, we are finalizing the 33 measures in Table 1 to establish the quality performance standards that ACOs must meet in order to be eligible for shared savings.

In the proposed rule, we considered two alternative options for establishing quality performance standards for the measures: Rewards for better performance, and a minimum quality threshold for shared savings. We proposed the performance score approach and sought comment on the threshold approach. The performance score approach would reward ACOs for better quality with larger percentages of shared savings. The threshold approach would ensure that ACOs exceed minimum standards for the quality of care, but allows full shared savings if ACOs meet the minimum level of performance.

b. Performance Scoring

Under the proposed rule, quality performance standards would be used to arrive at a total performance score for an ACO. We proposed to organize the measures by domain, and to score the performance on each measure. We proposed to roll up the scores for the measures in each domain into domain scores and to provide ACOs with performance feedback at both the individual measure and domain level. We proposed that the percentage of points earned for each domain would be aggregated using a weighting method to arrive at a single percentage that would be applied to determine the final sharing rate used to determine any shared savings or losses. We proposed that the aggregated domain scores would determine the ACO's eligibility for sharing up to 50 percent of the total savings generated by the ACO under the one-sided model or 60 percent of the total savings generated by the ACO under the two-sided risk model. We also discussed our proposal to set the quality performance standard in the first year of the Shared Savings Program at the complete and accurate reporting level and set the standard at a performance level in subsequent years.

(1) Measure Domains and Measures Included in the Domains

The proposed quality performance standard measures in Table 1 were subdivided into 5 domains, including: (1) Patient/Caregiver Experience; (2) Care Coordination; (3) Patient Safety; (4) Preventive Health; and (5) At-Risk Population/Frail Elderly. We proposed that the At-Risk Population/Frail Elderly domain would include a frail elderly category as well as the following chronic diseases: Diabetes mellitus; heart failure; coronary artery disease; hypertension and chronic obstructive pulmonary disorder.

(2) Methodology for Calculating a Performance Score for Each Measure Within a Domain

We proposed that an ACO would receive a performance score on each proposed measure. For the first year of the Shared Savings Program, these scores would be for informational purposes, since we proposed to set the quality performance standard at the reporting level. For subsequent years of the program, we proposed setting benchmarks for each measure using national Medicare FFS claims data, MA quality performance rates, or, where appropriate, the corresponding national percent performance rates that an ACO will be required to demonstrate. For each measure, we proposed to set a performance benchmark and a minimum attainment level as defined in Table 3 of the proposed rule (76 FR 19595). We proposed that the benchmarks would be established using the most currently available data source and most recent available year of benchmark data prior to the start of the Shared Savings Program annual agreement periods. We would determine Medicare FFS rates by pulling a data sample and modeling the measures. For

MA rates, we would check the distribution from the most recent available annual MA quality performance data for all MA plans and set the benchmark accordingly. Furthermore, since MA quality performance rates utilize both claims and clinical data, we proposed to use those rates when they are available.

We proposed that benchmark levels for each of the measures included in the quality performance standard would be made available to ACOs, prior to the start of the Shared Savings Program and each annual performance period thereafter, so ACOs would be aware of the benchmarks they must achieve to receive the maximum quality score. In the proposed rule, we stated that in future program years, we anticipate incorporating actual ACO performance to update the national benchmarks.

We also proposed that if an ACO fails to meet quality performance standard during a performance year (that is, fails to meet, the minimum attainment level for one or more domain(s)), we would give the ACO a warning, provide an opportunity to resubmit, and reevaluate the ACO's performance the following year. If the ACO continues to significantly under-perform, the agreement may be terminated. We further proposed that ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit may be terminated from the program. We noted that since meeting the quality standard is a condition for sharing in savings, the ACO would be disqualified from sharing in savings in each year in which it underperforms.

We proposed that performance below the minimum attainment level would earn zero points for that measure under both the one-sided and two-sided risk models. We also proposed that performance equal to or greater than the minimum attainment level but less than the performance benchmark would receive points on a sliding scale based on the level of performance, for those measures in which the points scale applies. We also proposed setting the initial minimum attainment level for both the one-sided and two-sided shared savings models at a 30 percent or the 30th percentile of national Medicare FFS or the MA rate, depending on what performance data are available.

We proposed ''all or nothing'' scoring for the diabetes and CAD composite measures. We proposed that measures designated as all or nothing measures would receive the maximum available points if all criteria are met and zero points if at least one of the criteria are not met. We defined ''all or nothing'' scoring to mean all of the care process steps and expected outcomes for a particular beneficiary with the target condition must be achieved to score positively. This means all sub measures within the diabetes and CAD composites would need to be reported in order to earn any credit for these measures. We stated we recognized that all or nothing scoring implies that all beneficiaries can and should receive the indicated care process, which may not necessarily be appropriate for all beneficiaries. As a result, we also proposed scoring the diabetes and CAD sub measures individually. We also proposed a HAC composite measure for which we did not propose all or nothing scoring, since the HACs are rare events.

We also stated our intent to post performance rates for the final measures set, including the applicable benchmarks, on the CMS Web site prior to the start of the first performance period.

(3) Methodology for Calculating a Performance Score for Each Domain

Similar to our proposal for setting a quality standard for each individual measure at the reporting level in the first program year, we also proposed setting a quality standard for each domain at the reporting level. For subsequent program years, we proposed to calculate the percentage of points an ACO earns for each domain after determining the points earned for each measure. We planned to divide the points earned by the ACO across all measures in the domain by the total points available in that particular domain. Each domain would be worth a predefined number of points based on the number of individual measures in the domain.

We proposed that under both the one-sided and two-sided shared savings models, the quality measures domain scoring methodology would treat all domains equally regardless of the number of measures within the domain. We stated in the proposed rule that we believed the key benefit of weighting the domains equally is that it would not create a preference for any one domain, which we consider important as we expect ACOs to vary in composition, and, as a result, to place more emphasis on different domains. Furthermore, we want to encourage a diverse set of ACOs and believe that emphasizing certain domains over others would encourage a certain type of ACO to participate but discourage other types from participating.

We proposed to aggregate the quality domain scores into a single overall ACO score which would be used to calculate the ACOs final sharing rate for purposes of determining shared savings or shared losses. All domain scores for an ACO would be averaged together equally to calculate the overall quality score that would be used to calculate the ACO's final sharing rate used to determine the amount of shared savings or losses an ACO would receive or owe. We also proposed that ACOs must report completely and accurately on all quality measures within all domains to be deemed eligible for shared savings consideration. Finally, we stated we also considered scoring measures individually under a method that weights measures equally as well as an approach that would weight quality measures by their clinical importance.

(4) The Quality Performance Standard Level

We proposed to set the quality performance standard for the first year of the Shared Savings Program at the reporting level. That is, under the one-sided model, we proposed that an ACO would receive 50 percent of shared savings (provided that the ACO realizes sufficient cost savings under) based on 100 percent complete and accurate reporting on all quality measures. Similarly, we proposed that under the two-sided risk model, ACOs would receive 60 percent of shared savings (provided that the ACO realizes sufficient cost savings) based on 100 percent complete and accurate reporting on all quality measures. We stated that setting the quality performance standard for the first year of the Shared Savings Program at full and accurate reporting would allow ACOs to ramp up, invest in their infrastructure, engage ACO providers/suppliers, and redesign care processes to capture and provide data back to their ACO providers/suppliers to transform care at the point of care. We also noted that setting the quality performance standard at the reporting level would be consistent with other value-based purchasing programs that started as pay for reporting programs.

We indicated that we planned to raise the quality performance standard requirements in future years through future rulemaking, when actual performance on the reported measures would be considered in establishing the quality benchmarks (in addition to the national flat percent or FFS/MA percentile). We stated in the proposed rule that we believe this approach would be consistent with section 1899(b)(3)(C) of the Act, which requires that the Secretary ''seek to improve the quality of care furnished by ACOs over time by specifying higher standards,

new measures, or both for the purposes of assessing such quality of care.''

While we proposed the performance scoring methodology, we also considered adopting a minimum quality threshold to assess the performance of participating ACOs, as described in the proposed rule (76 FR 19597–98).

Comment: A few commenters suggested weighting each domain equally or balancing the number of measures in each domain to prevent any single measure from having a greater impact on the overall score. Another commenter stated that proposed measures are unfairly weighted and measured. One commenter believed process measurements should be scored higher since they are under provider control, whereas another commenter suggested that outcome measures be weighted heavier than structure and process measures. One commenter thought the measures should be more evenly distributed across the 5 equally weighted domains, so that domains with fewer measures do not have a greater impact on overall score. A few commenters did not agree with measures having equal weighting. One commenter recommended that the Patient/Caregiver Experience and Care Coordination domains be more heavily weighted as they are the foundation for improving process and outcomes, while another commenter stated the domains of care coordination and patient caregiver experience are untested.

One commenter suggested scoring clinical process measures individually rather than by domain. A number of commenters thought the proposed approach would exclude a large number of ACOs from sharing in savings even though they were providing high quality care. Many commenters took issue with the notion that failing to attain the standard for one single measure would eliminate the possibility for sharing in any savings and recommended that the threshold be set at the domain level rather than the individual measure level. One commenter suggested CMS provide each ACO with their historical 50th percentile for each quality metric which the ACO would have to exceed in each domain to fully share in savings. For each domain that exceeded benchmark, this commenter recommended the ACO's share of savings would increase by 20 percent but the ACO would still be responsible for shared losses under the two-sided model.

Response: We believe that all 4 domains we are adopting in this final rule are of considerable importance and, therefore, agree with the comments that supported weighting each domain equally and will finalize our proposal to do so. This means the 4 measure domains (patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population) will be weighted at 25 percent each in calculating an ACO's overall quality performance score for purposes of determining its final sharing rate. Additionally, we are finalizing the following disease categories within the At-Risk population domain: Diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease.

Equally weighting the measure domains, and individual measures within the domains, is consistent with our view that all of these domains are important to achieving the Medicare Shared Savings Program goals and should be a focus of ACOs, with the exception of the measure, Percent of PCPs who Successfully Qualify for an EHR Incentive Payment. We are double-weighting this measure, as discussed in section II.F. of this final rule, in an effort to signal the importance of EHR adoption to ACOs for achieving success in the Shared Savings Program. We note that, since the Shared Savings Program has not yet begun and ACOs have not yet formed, we are unsure how we could provide any ACO historical data on its quality performance since it would require participating organizations to submit a historical baseline for quality which we believe would add unnecessary burden to newly forming ACOs.

Comment: Many commenters suggested CMS reward a higher level of quality and not just a threshold. Several commenters expressed concern that the quality points scale failed to reward ACOs who are already providing high quality, efficient care in the first year and fails to reward high performance, as opposed to minimum threshold, in subsequent years.

Response: We believe the proposed approach offers a greater incentive for continuous quality improvements, since it has a sliding scale in which higher levels of quality performance translate to higher sharing rates. High performing ACOs should do well under this approach since it recognizes and provides incentives for ACOs to maintain high quality performance in order to maximize their sharing of savings and minimize their sharing of losses.

Comment: Many commenters took issue with the proposed 30 percent/30th percentile threshold. Several commenters stated that if CMS establishes benchmarks solely on the participating ACOs, it would be unfair to assume the bottom 30 percent should receive no credit toward retaining savings when they may very well be performing well above the rest of the nation. Several commenters suggested CMS should, instead, establish specific thresholds for each measure such as a certain percentage with blood pressure under control or a certain percentage improvement, particularly for measures which have not been validated or are not in widespread use among Medicare beneficiaries. However, another commenter suggested a minimum attainment level higher than the 30th percentile in order to best promote quality improvement. One commenter suggested maintaining the proposed approach to score individual measures on a continuum between a threshold (lower bound) and benchmark (upper bound). One commenter suggested rewarding performance in the middle range of quality improvement more than the upper target and lower threshold by taking an average of high and low performers' scores. A couple of commenters noted that without known targets it will be difficult for ACOs to know whether they will be able to achieve the quality performance standards. These commenters requested that we publish specific thresholds in the final rule so that ACOs will know before applying for the program whether they have a reasonable likelihood of success. One commenter suggested establishing performance thresholds and rewarding those ACOs that achieve or make improvements toward those thresholds while another recommended establishing specific numerical targets for all laboratory-based measures. One commenter advocated for gradual increases in the minimum attainment level so that health care organizations are encouraged to continually improve, with clear delineation and rewards for the high performers.

Response: We are finalizing our proposal to establish the minimum attainment level for a measure at a national flat 30 percent or where applicable the national 30th percentile level of performance of FFS or MA quality rates, because we believe this level is reasonable and achievable given current levels of performance on measures in other programs and based on measure community research. As previously discussed, the first year of the agreement period will be pay for reporting only, so ACOs would earn their maximum sharing rate for completely and accurately reporting 100 percent of the required data. We plan to release performance benchmarks in sub regulatory guidance at the start of the

second year of the performance period as we phase in measures to pay for performance so that ACOs are aware of the actual performance rates they will need to achieve to earn the maximum quality points under each domain. We agree with the comment suggesting we gradually raise the minimum attainment level in order to continue to incentivize quality improvement over time and would do so through future rulemaking after providing sufficient advance notice with a comment period to first gain industry input. We note that performance will be rewarded on a scale such that levels of quality improvement between an upper and lower threshold are rewarded. This scale also rewards higher improvement over time, since higher performance translates to higher shared savings. For example, an ACO that performs at 80 percent/80th percentile one year and then at 90 percent/90th percentile the next year, would receive a higher level of shared savings in their second year than in their first year, based on their improved quality performance.

Comment: One commenter suggested using the first 2 years of ACO performance data to establish performance benchmarks, rather than the first year only, since the first year will require ACOs to develop infrastructure and reporting systems. A couple of commenters suggested calculating regional benchmarks so ACOs have a similar chance of achieving success regardless of geographic location. One of these commenters recommended benchmarking at the geographic unit level MedPAC has recommended for MA payments and thought benchmarks should not be based on ACO providers/suppliers alone. One commenter recommended that the benchmark should be based on comparable, local, non-assigned, FFS beneficiaries. However, another commenter thought benchmarks should be based on a comparison of ACOs to other ACOs or Medicare FFS but not MA. The commenter thought it would be inequitable to compare ACOs to the MA program, since patients are locked-in to providers under MA and cannot change providers, unlike an ACO model under which patients are free to seek care outside of the ACO. One commenter suggested an evidence-based approach to any benchmark changes. One commenter recommended CMS specify in the final rule whether FFS or MA data would serve as the basis for benchmarks. This commenter advocated for use of FFS data since these data are more directly relevant to the target population from which the ACO population is derived. One commenter stated that relying on existing data sources for measures would have the advantage of allowing benchmarks to be determined from program onset. This commenter also believed that having a fixed set of performance targets around which the ACO can plan its work is essential to the program's success and that targets should not vary from year to year although the commenter did suggest a range (for example, good to great) be established and incentives set accordingly. One commenter asked for clarification about how benchmarks would be developed for proposed measures that do not have historical data. One commenter requested alignment of the scoring methodology with value-based purchasing.

Response: We are finalizing our proposal to establish national benchmarks for quality measures using a national sample of Medicare FFS claims data, M A quality data, or a flat percentage if FFS claims/MA quality data are not available. We believe national benchmarks are more appropriate than regional benchmarks, since Medicare FFS is a national program and we would like to measure quality improvement and make comparisons over time between FFS and ACO populations on a national basis. Regarding the comment asking how we would develop benchmarks for measures in which claims or MA quality data are not available, we would use a flat national percent establishing the minimum at 30 percent and the maximum at 90 percent as indicated in Table 3. We plan to release benchmarking data in subregulatory guidance and expect to align with other pay for performance program benchmarking methodologies over time. At this time, we are not proposing to compare an ACO's quality performance to the performance of other ACOs for purposes of determining an ACO's overall quality score and final sharing rate. We agree that we should seek to incorporate actual ACO performance on quality scores into the quality benchmark, however, we would do so in future rulemaking and then only after seeking industry input. In addition, we do expect to update the benchmarks over time, consistent with section 1899(d)(3)(C) of the Act, which requires CMS to seek to improve the quality of care over time.

Comment: Several commenters recommended a sliding scale in lieu of complete and accurate reporting. One commenter recommended the standard for complete and accurate reporting should be 95 to 100 percent and the threshold should be between the 70th and 100th percentile. A few commenters suggested CMS consider the PQRS experience with reporting; one mentioned that CMS lowered the PQRS reporting threshold from 80 to 50 percent for its claims based reporting option and kept the registry reporting threshold at 80 percent. A couple of commenters requested clarification on what would constitute a ''reasonable explanation'' for an ACO not to report quality data. A number of commenters thought the proposed approach would exclude a large number of ACOs from sharing in savings even if they provided high quality care. Many commenters took issue with the notion that failing to attain the standard for one single measure should eliminate the possibility of sharing in any savings. One commenter recommended CMS give ACOs credit for measures on which the ACO scored well, even if it does not meet the threshold for other measures within the domain, perhaps by setting the threshold at the domain level rather than the measure level. This commenter stated this was particularly important early in the program, when ACOs may not have experience with the measures, the specifications may have been modified, and the thresholds setting methodology is new and untested.

Response: While it is our intent that ACOs raise the bar in terms of quality of care improvement and performance, and although we believe 100 percent complete and accurate reporting can be achieved for the measures we are finalizing, we are sensitive to comments suggesting we have modified this final rule to allow ACOs more time to ramp up. As a result, we have modified this final rule to provide a longer phase in to pay for performance. All 33 measures used for scoring purposes will be pay for reporting in year 1 of the agreement. In year 2, 8 measures will continue to be pay for reporting, while 25 measures will be used for pay for performance. In year 3 (and 4 if applicable), 32 measures will be pay for performance and 1 measure, the health status/functional status module will be pay for reporting.

Final Decision: We recognize that achieving the quality performance standard on 33 out of 33 measures may be difficult especially in the early years. Accordingly, we have modified this final rule to require that ACOs achieve the quality performance standard on 70 percent of the measures in each domain. If an ACO fails to achieve the quality performance standard on at least 70 percent of the measures in each domain we will place the ACO on a corrective action plan and re-evaluate the following year. If the ACO continues to

underperform in the following year, the agreement would be terminated. We believe requiring ACOs to achieve the quality performance standard on 70 percent of the measures in each of the 4 domains establishes a feasible standard, while signaling to providers that they need to devote significant focus to performance in each domain.

This approach also means that an ACO could fail one or more individual measures in each domain measure and still earn shared savings. ACOs must achieve the minimum attainment level on at least 70 percent of the measures in each domain in order to continue in the program. As described in section II.H. of this final rule, if an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in each domain, we will give the ACO a warning, an opportunity to resubmit and re-evaluate the following year. If the ACO continues to underperform in the following year, the agreement would be terminated. However, in any year that an ACO scores a zero for an entire measure domain, it would not be eligible to share in any savings generated. It should also be noted that if an ACO fails to completely and accurately report the EHR measure, the ACO would miss the 70 percent cut-off for the Care Coordination domain, since this measure is double-weighted for both scoring purposes and for purposes of determining poor performance.

We are also finalizing our proposal that if an ACO fails to report one or more measures, we will send the ACO a written request to submit the required data by a specified date and to provide reasonable explanation for its delay in reporting the required information. If the ACO fails to report by the requested deadline or does not provide a reasonable explanation for delayed reporting, we would immediately terminate the ACO for failing to report quality measures. ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit may be terminated from the program. An ACO that has been terminated from the program is disqualified from sharing in savings.

TABLE 3—SLIDING SCALE MEASURE SCORING APPROACH

ACO performance level	Quality points (all measures except EHR)	EHR measure quality points
90+ percentile FFS/MA Rate or 90+ percent	2 points	4 points.
80+ percentile FFS/MA Rate or 80+ percent	1.85 points	3.7 points.
70+ percentile FFS/MA Rate or 70+ percent	1.7 points	3.4 points.
60+ percentile FFS/MA Rate or 60+ percent	1.55 points	3.1 points.
50+ percentile FFS/MA Rate or 50+ percent	1.4 points	2.8 points.
40+ percentile FFS/MA Rate or 40+ percent	1.25 points	2.5 points.
30+ percentile FFS/MA Rate or 30+ percent	1.10 point	2.2 points.
<30 percentile FFS/MA Rate or <30 percent	No points	No points.

TABLE 4—TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (Table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (percent)
Patient/Caregiver Experience	7	1 measure with 6 survey module measures combined, plus 1 individual measure.	4	25
Care Coordination/Patient Safety.	6	6 measures, plus the EHR measure double-weighted (4 points).	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25
Total	33	23	48	100

As illustrated in Table 4, a maximum of 2 points per measure could be earned under both the one-sided and two-sided model based on the ACO's performance, except on the EHR measure, which is weighted double any other measure and would be worth 4 points. We believe EHR adoption is important for ACOs to be successful in the Shared Savings Program and are double weighting this measure as a way to signal this and provide incentive for greater levels of EHR adoption.

However, the total potential for shared savings will be higher under the two-sided model, since the maximum potential shareable savings based on quality performance is 60 percent of the savings generated, compared to 50 percent under the one-sided model, as discussed in section II.G. of this final rule. That is, 100 percent reporting of the quality measures in the first year of the Shared Savings Program will result in an ACO earning 50 or 60 percent of shareable savings, depending on whether the ACO is in the one-sided or two-sided model. For future performance periods, the percent of potential shareable savings will vary based on the ACO's performance on the measures as compared with the measure benchmarks as we phase in the pay for performance measures, as shown in Table 2.

We are establishing the minimum attainment level for each measure at a national flat 30 percent or the national Medicare FFS or MA 30th percentile level of performance, as proposed. We believe this level is reasonable and achievable given current levels of performance on measures in other programs and based on measure community research. ACOs will have to score at or above the minimum attainment level in order to receive any credit for reporting the quality measure. We will release corresponding national benchmarks, based on Medicare FFS claims data, Medicare Advantage quality data, or a flat percentage if claims/quality data are not available in

subregulatory guidance at the start of the second performance period and, when certain measures move to pay for performance.

We are also finalizing our proposal for scoring individual measures in each domain in pay for performance years. Based on their level of performance on each measure an ACO would earn the corresponding number of points as outlined in Table 3. The total points earned for measures in each domain would be summed up and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available.

We are finalizing our proposal to weight each of the 4 measure domains (patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population) equally at 25 percent for purposes of determining an ACO's overall quality performance score. We believe giving equal weight to the domains will signal the equal importance of each of these areas and to encourage ACOs to focus on all domains in order to maximize their sharing rate. Accordingly, the percentage score for each domain, calculated using the methodology described previously, will be summed and divided by 4 to reflect the equal weighting of the domains. The resulting percentage will then be applied to the maximum sharing rate under either the one-sided or two-sided model to determine the ACOs final sharing rate for purposes of determining its shared savings payment or share of losses.

5. Incorporation of Other Reporting Requirements Related to the PQRS and Electronic Health Records Technology Under Section 1848 of the Act

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from these programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to ''* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *'' and permits the Secretary to ''use alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments.'' Under this authority, we proposed to incorporate certain reporting requirements and payments related to the PQRS into the Shared Savings Program for ''eligible professionals'' within an ACO (76 FR 19598). Under section 1848(k)(3)(B) of the Act, the term ''eligible professional'' means any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech pathologist; or (4) a qualified audiologist.

We proposed to incorporate a PQRS GPRO under the Shared Savings Program and further proposed that EPs that are ACO participant providers/suppliers would constitute a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program (76 FR 19599). Specifically, we proposed that EPs would be required to submit data through the ACO on the quality measures we proposed (76 FR 19571) to qualify for the PQRS incentive under the Shared Savings Program. We proposed that the ACO would report and submit data on behalf of the EPs in an effort to qualify for the PQRS incentive as a group practice; that is, EPs within an ACO would qualify for the PQRS incentive as a group practice, and not as individuals. In addition, we proposed a calendar year reporting period from January 1 through December 31, for purposes of the PQRS incentive under the Shared Savings Program. With regard to the incorporation of criteria for satisfactory reporting for purposes of the PQRS incentive for the first performance period under the Shared Savings Program, we proposed that:

- An ACO, on behalf of its EPs, would need to report on all measures included in the data collection tool;
- Beneficiaries would be assigned to the ACO using the methodology described in the Assignment section of the proposed rule. As a result, the GPRO tool would be populated based on a sample of the ACO-assigned beneficiary population. ACOs would need to complete the tool for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measures set, or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex. If the pool of eligible assigned beneficiaries is less than 411, the ACO would report on 100 percent of assigned beneficiaries for the domain, measure set, or individual measure.
- The GPRO tool would need to be completed for all domains, measure sets, and measures described in Table 1 of the proposed rule.

Accordingly, we proposed that EPs within an ACO that satisfactorily report the proposed measures during the reporting period would qualify under the Shared Savings Program for a PQRS incentive equal to 0.5 percent of the Secretary's estimate of total Medicare Part B PFS allowed charges for covered professional services furnished by the ACO's EPs during the first performance period. ''Covered professional services'' are services for which payment is made under, or based on, the physician fee schedule and which are furnished by an eligible professional under the ACO participant's TINs.

We proposed to align the incorporated PQRS requirements with the general Shared Savings Program reporting requirements, such that no extra reporting would actually be required in order for EPs or the ACO to earn the PQRS incentive under the Shared Savings Program. Thus, for ACOs that meet the quality performance standard under the Shared Savings Program for the first performance period, we proposed that the PQRS EPs within such ACOs will be considered eligible for the PQRS incentive under the Shared Savings Program for that year. In the proposed rule, we stated that this means ACOs would need to report on all measures proposed (76 FR 19571) in order to receive both the Shared Savings Program shared savings and PQRS incentive (76 FR 19599). We also stated that failure to meet the Shared Savings Program quality performance standard would result in failure to be considered eligible for shared savings, as well as failure for the EPs within the ACO to receive a PQRS incentive under the Shared Savings Program for that year. ACO participant provider/suppliers who meet the quality performance standard but do not generate shareable savings would still be eligible for PQRS incentive payments. We also indicated that we intended to discuss the policy for incorporating the PQRS incentive under the Shared Savings Program for subsequent years in future rulemaking (76 FR 19599).

We noted in the proposed rule that ACOs would be eligible for the PQRS incentive under the Shared Savings Program to the extent that they contain EPs as defined under § 414.90(b). As a result, not all ACOs would necessarily be eligible for the PQRS incentive under the Shared Savings Program. A complete list of PQRS EPs (EP) is available at: *http://www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf.* In addition, similar to traditional PQRS, we indicated that an EP could not

qualify for the PQRS incentive as both a group that is part of an ACO and as an individual. Furthermore, EPs could not qualify for a PQRS incentive under both the PQRS under the Shared Savings Program and the traditional PQRS under the same TIN. For purposes of PQRS incentive analysis and payment, we stated that we intended to use TINs and NPI numbers similar to what we have done in the traditional PQRS (75 FR 40169), and we would provide such details in guidance (76 FR 19599). We invited comment on our proposal to incorporate PQRS requirements and payments under the Shared Savings Program.

We did not propose to incorporate payments for the EHR Incentive Program or eRx Incentive Program under the Shared Savings Program. Professionals in ACOs may still separately participate in the EHR Incentive Program or Electronic Prescribing Incentive Program. However, we proposed to require for the Shared Savings Program measures also included in the EHR Incentive Program and metrics related to successful participation in the Medicare and Medicaid EHR Incentive Programs for EPs and hospitals and the eRx Incentive Program.

In addition, as a Shared Savings Program requirement separate from the quality measures reporting, we proposed requiring that at least 50 percent of an ACO's primary care physicians be determined to be ''meaningful EHR users'' as that term is defined in 42 CFR 495.4 by the start of the second performance year in order to continue participation in the Shared Savings Program. The EHR Incentive regulations, including the definition of meaningful EHR user and certified EHR technology can be found at 42 CFR part 495, as published on July 28, 2010 (75 FR 44314). The preamble to the July 28, 2010 final rule also describes the stages of meaningful use. We also sought comment on whether we should also specify a percentage-based requirement for hospitals. Such a requirement would be similar to the previous proposal for primary care physicians and would require 50 percent of eligible hospitals that are ACO providers/suppliers achieve meaningful use of certified EHR technology by the start of the second performance year in order for the ACO to continue participation in the Shared Savings Program. We also requested public comment related to circumstances where the ACO may include only one eligible hospital or no hospital and whether we would need to provide an exclusion or exemption in such a circumstance.

Comment: A few commenters specifically commended CMS's alignment of the ACO quality reporting requirements with PQRS reporting requirements. A few commenters recommended a single reporting process for the measures common to PQRS, ACO, and the EHR Incentive programs to reduce burden and duplication of effort. However, one commenter recommended separate reporting for the Shared Savings Program quality performance standard and the PQRS satisfactory reporting requirement initially until experience with the measures ACOs report for shared savings eligibility purposes demonstrates reliability for both ACO and PQRS needs. One commenter suggested individual PQRS reporting for providers who may be in more than one ACO. One commenter supported alignment with traditional PQRS GPRO reporting and suggested a financial disincentive for non-compliance. One commenter believed that individual EPs should be allowed to submit quality measures data to the traditional PQRS without participating in ACOs. Another commenter expressed concern that professionals could be confused by reporting ACO PQRS measures via GPRO for their ACO patients if they are also reporting PQRS measures via claims or a registry for patients not in the ACO under the traditional PQRS program.

Response: We agree with the recommendations to streamline reporting as much as possible and are finalizing a set of measures aligned with other programs, such as the PQRS, EHR Incentive Program, and PGP Transition Demonstration. In order to reduce reporting burden and decrease operational complexity for purposes of earning the PQRS incentive under the Shared Savings Program, we are modifying our proposal. Although we are requiring that EPs in ACOs meet the criteria for satisfactory reporting by reporting data on all of the final ACO GPRO measures, we are not finalizing our proposal to condition the PQRS incentive payment on the reporting of all of the other ACO quality measures (that is from claims, CAHPS, and CMS administrative data) under the Shared Savings. That is, if an ACO, on behalf of its EPs, satisfactorily reports ACO GPRO measures, the EP's ACO participant TIN will receive the PQRS incentive even if the ACO does not meet the quality performance standards and lower growth in costs requirements to share in savings under the Shared Savings Program. EPs in an ACO that starts its agreement in April or July 2012 will also qualify for the 2012 PQRS incentive under the Shared Savings Program by satisfactorily reporting the ACO GPRO measures for the full 2012 PQRS calendar year reporting period.

We believe only requiring EPs in ACOs to meet the criteria for satisfactory reporting by reporting data on all of the final ACO GPRO measures reduces reporting burden, since we are simplifying the requirements EPs in ACOs must meet to earn a PQRS incentive under the Shared Savings Program. It also increases the probability that an EP would receive some level of incentive under the Shared Savings Program. We believe requiring ACOs to report the final GPRO measures, as opposed to all of the final ACO quality measures, to earn a PQRS incentive under the Shared Savings Program also reduces operational complexity because CMS can calculate the incentive payment under the Shared Savings Program based on the GPRO quality data after the ACO completes the GPRO quality data submission. That is, the calculation and distribution of the PQRS incentive will not be contingent on our analysis of other ACO quality data from claims, CAHPS and CMS administrative data under the Shared Savings Program. Requiring ACOs to report a full 12 months of GPRO quality data also aligns the reporting period for earning a PQRS incentive under the Shared Savings Program with the traditional PQRS. In addition, we believe groups that are currently participating under the traditional PQRS GPRO, but are considering participating in the Shared Savings Program, would have greater assurance they could earn a PQRS incentive under the Shared Savings Program, given that we are not finalizing our proposal that ACOs comprised of such group practices must also meet other Shared Savings Program requirements for a shared savings payment for purposes of earning a PQRS incentive.

We also wish to clarify that ACO participant TINs that wish to qualify for PQRS would need to participate as group practices in the PQRS under the Shared Savings Program and may not separately participate in or earn a PQRS incentive under the traditional PQRS, outside of the Shared Savings Program. In addition, individual ACO providers/suppliers who are EPs in an ACO participant TIN may not seek to qualify for an individual PQRS incentive under the traditional PQRS. We do not agree with the suggestion that ACO providers/suppliers, who are EPs in one or more ACOs, be allowed to do individual PQRS reporting—in either the traditional PQRS or the PQRS under the

Shared Savings Program—for two main reasons. First, the Shared Savings Program is concerned with measuring the quality of care furnished by the ACO as a whole, and not that of individual ACO providers/suppliers. Second, allowing provider/suppliers to earn more than one PQRS incentive goes against the rules of traditional PQRS. We do not agree with the comment that disincentives for non-participation are necessary at this point. Rather, we believe positive rewards for successful Shared Savings Program and PQRS participation will be more instrumental in achieving the desired outcomes.

Comment: A few commenters recommended CMS assure that attestation through the EHR Incentive Programs will serve as reporting for the ACO program or that participation in ACO electronic quality measurement reporting as one avenue of fulfilling meaningful use criteria under the EHR Incentive Program. One of these commenters also suggested that CMS should facilitate one-time data extraction to fulfill multiple programs' reporting requirements.

Response: At this time, the EHR Incentive Program does not have a mechanism for group reporting, so we are unable to translate quality data that ACOs will report as a group under the Shared Savings Program to individual EHR incentives for EPs. The PQRS does allow for group reporting, which is why we are able to incorporate and align such reporting and incentive payments under the Shared Savings Program.

Comment: While one commenter supported the proposal that 50 percent of an ACO's primary care providers be meaningful EHR users by the start of the second performance year, many commenters stated that the initial 50 percent bar is too high given the lack of experience with the EHR Incentive Programs, especially for smaller, less integrated practices and those in rural areas. One commenter did not believe that the Shared Savings Program should serve to increase the rigor of other CMS programs or that lack of participation in the EHR incentive programs should preclude participation in the Shared Savings Program. Some commenters noted that CMS already is providing incentives for meaningful use of certified EHR technology, making inclusion of such a requirement under the Shared Savings Program redundant and unnecessary. Several commenters suggested phasing in this requirement, potentially over a 5-year period, or through certain annual percentages starting in year two. Other commenters suggested delaying or lowering the threshold, creating exceptions (such as hardship exceptions) or opportunities for corrective action, excluding from the requirement professionals who are ineligible for the EHR Incentives, expanding the scope more broadly than primary care physicians, including hospitals in the final rule, or generally allowing ACOs to establish their own goals for meaningful use. Commenters expressed concern about the stages of meaningful use and which stage would have to be met by the second year of a given ACO's agreement with CMS, particularly if the second year began on January 1, 2014.

Response: We have modified our proposal such that EHR participation is no longer a condition of participation but remains one of our quality measures. In addition, we have clarified that the measure will include any PCP who successfully qualifies for an EHR Incentive Program incentive. We believe this change is consistent with industry comments, recognizes ACOs providers' current levels of EHR Incentive Program participation, rewards higher adoption with higher sharing rates, and signals the importance of EHR adoption to ACOs. To further signal the importance of EHRs we will score the EHR quality measure with higher weight than the other quality measures. Although we are not finalizing the requirement that 50 percent of PCPs in ACOs be meaningful users in order for the ACO to be eligible to continue to participate for a second year in the Shared Savings Program, we recognize that ACOs with more IT infrastructure integrated into clinical practice will likely find it easier to be successful under the Shared Savings Program. As providers gain more experience with EHR technology, we will reconsider using certified EHR technology as an additional reporting mechanism used by ACOs under the Shared Savings Program, which we would address in rulemaking for future program years.

In the proposed rule, we also indicated that ACOs would need to participate separately in the eRx Incentive Program (76 FR 19599). We strongly recommend that potential ACOs review the CY 2012 Physician Fee Schedule eRx Incentive Program proposed and final rules carefully, for details about participation requirements, self-nomination timeframes, incentive payments and penalties. The CY 2012 Physician Fee Schedule eRx Incentive Program proposed rule is available at: *http://www.gpo.gov/fdsys/pkg/FR-2011-07-19/pdf/2011-16972.pdf.*

Final Decision: After considering the issues raised in the public comments and for the reasons we previously discussed, we are finalizing our proposal to incorporate PQRS reporting requirements and incentive payment under the Shared Savings Program. Specifically, in this final rule we are finalizing the use of the GPRO web interface, as proposed, as well as our proposal that EPs that are ACO providers/suppliers constitute a group practice under their ACO participant TIN for purposes of qualifying for a PQRS incentive under the Shared Savings Program. Therefore, an ACO, on behalf of its EPs, is required to satisfactorily submit quality data on the GPRO quality measures we are finalizing in Table 1 of this final rule. Such EPs within an ACO may qualify for a PQRS incentive under the Shared Savings Program only as a group practice and not individuals. ACO participants and ACO providers/suppliers also may not seek to qualify for the PQRS incentive under traditional PQRS, outside of the Shared Savings Program. We are also finalizing the calendar year reporting period of January 1 through December 31 for purposes of the PQRS incentive under the Shared Savings Program.

Furthermore, we intend that reporting on the GPRO quality measures under the Shared Savings Program will also fulfill the reporting requirements for purposes of avoiding the payment adjustment under section 1848(a) of the Act that begins in 2015. We plan to address this issue in more detail in future rulemaking.

With regard to the GPRO quality measures applicable for the PQRS incentive under the Shared Savings Program, we are finalizing the PQRS GPRO criteria for satisfactory reporting as described previously.

Accordingly, EPs within an ACO participant TIN that satisfactorily report the ACO GPRO measures during the reporting period will qualify under the Shared Savings Program for a PQRS incentive equal to 0.5 percent of the Secretary's estimate of total Medicare Part B PFS allowed charges for covered professional services furnished by the ACO's EPs during the first reporting period. ''Covered professional services'' are services for which payment is made under, or based on, the physician fee schedule and which are furnished by EPs (under the ACO participant's TINs).

By satisfactorily reporting the ACO GPRO measures on behalf of the EPs in the group practice, we note that the ACO participant TIN will meet the requirements for the PQRS incentive payment and also fulfill a portion of the quality performance standard requirements for purposes of Shared Savings Program shared savings

eligibility. However, ACOs must also completely and accurately report all of the measures in Table 1, as well as meet the lower growth in costs criteria, described in section II.G. of this final rule, to be considered eligible for shared savings.

As we indicated previously, we are not finalizing our proposal regarding an ACO's failure to report all required ACO quality measures. That is, if an ACO fails to meet the Shared Savings Program quality performance standard and is not eligible for shared savings, EPs in a group practice that is an ACO participant TIN may nevertheless earn the PQRS incentive under the Shared Savings Program, as long as the ACO satisfactorily reports, on behalf of its EPs, the ACO GPRO quality measures for the reporting period. Thus, ACO participant TINs in ACOs that meet the satisfactory reporting requirements will still be eligible for a PQRS incentive payment under the Shared Savings Program, even if the ACO does not generate shareable savings for the Shared Savings Program.

As we indicated, ACOs are eligible to qualify for the PQRS incentive under the Shared Savings Program to the extent that they contain EPs as defined under § 414.90(b). As a result, not all ACO participants will necessarily be eligible for the PQRS incentive under the Shared Savings Program. A complete list of PQRS EPs is available at: *http://www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf.* In addition, similar to traditional PQRS, an EP cannot qualify for the PQRS incentive as both a group and as an individual under the same TIN. For purposes of PQRS incentive analysis and payment, we will use TINs and NPI numbers similar to what we have done in the traditional PQRS (75 FR 40169), and we will provide such details in guidance (76 FR 19599).

As we noted previously, we did not propose to incorporate the EHR Incentive Program or eRx Incentive Program reporting requirements or incentives under the Shared Savings Program. EPs in ACOs may still separately participate in the EHR Incentive Program or eRx Incentive Program, and we encourage potential ACOs to follow the applicable requirements for those programs.

We are also modifying our proposal regarding the EHR Incentive Program participation criteria as a condition of continued Shared Savings Program. We are not finalizing the proposal to require that at least 50 percent of an ACO's primary care physicians be determined to be ''meaningful EHR users'' as that term is defined in 42 CFR 495.4 by the start of the second performance year in order to continue participation in the Shared Savings Program. Instead we will double weight the quality measure ''Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment,'' as described previously in section II.F, to stress the importance of EHR adoption among ACOs.

6. Aligning ACO Quality Measures With Other Laws and Regulations

As we stated in the proposed rule, different quality frameworks and rewards may add to confusion and administrative burdens for affected parties, and mitigate efforts to focus on the highest-quality care. Therefore, we sought comment from affected parties and other stakeholders on the best and most appropriate way to align quality domains, categories, specific measures, and rewards across these and other Federal healthcare programs, to ensure the highest-possible quality of care. Specifically, we sought comment on whether quality standards in different Affordable Care Act programs should use the same definition of domains, categories, specific measures, and rewards for performance across all programs to the greatest extent possible, taking into account meaningful differences in affected parties.

Comment: A number of commenters supported aligning ACO quality measures with other CMS programs such as PQRS, eRx, Hospital Compare, Medicare Advantage, the upcoming physician fee schedule value modifier, and the EHR Incentive Programs to avoid burden, confusion duplicative reporting. One commenter suggested the EHR Incentive Program requirements are not aligned with ACO requirements, missing the opportunity to incentivize adoption and interoperability to lower costs and improve care. This commenter suggested that ACO standards be supported in the EHR Incentive Program. One commenter noted 'alignment' does not necessarily mean using exactly the same set of measures across programs, since ACOs may have data collection capabilities and needs that are broader than those applicable to the EHR incentive program, and the pools of provider participants in the two programs will be different. A few commenters recommended CMS make public its overall quality measurement strategy including the synergy between measures for ACOs, hospital IQR, and other initiatives. One commenter supported alignment with other programs but raised concerns about the fairness of resultant double jeopardy or double incentives. A few commenters expressed concern that the lack of complete alignment with MA 5 Star measures would result in increased burden of reporting and decreased performance, greater start-up costs, and hinder consumers' ability to make informed coverage choices. While one commenter believed measures reported through other programs should be excluded from this program, a number of commenters recommended that only those measures currently being reported in other CMS programs should be used initially although there were varying recommendations about with which program to align. One commenter recommended using the Hospital Quality Incentive Demonstration model as had succeeded in improving quality and decreasing cost. One commenter specifically recommended the ACO program begin exclusively with measures used in the PGP demonstration.

A few commenters believed it would be desirable to have a single set of quality measures across payers, including Medicaid, Medicare, and commercial payers; one noted this would benefit vendors, providers, and patients. A few commenters suggested alignment with non-federal programs. One commenter suggested ACO quality reports should explain differences in measures reported by CMS and those reported by Regional Health Improvement Collaboratives (RHICs). One commenter recommended CMS align measures with the goals and domains of the National Quality Strategy.

Response: We agree, in principle, with alignment across programs. To that end, we have chosen a final measure set that is closely aligned with PQRS as discussed previously. At this point in time and for this particular program, the ambulatory PQRS set was the natural choice compared with other proposed measurement sets focused on the inpatient setting or MA plans. However, we will revisit this issue and continue to work toward alignment with those and other programs in future rulemaking. We also do intend to further align the Shared Savings Program with the EHR Incentive Programs as we develop experience with both programs and EHRs become more widespread. We do not share the one commenter's concern about ''double jeopardy'' or ''double incentives'' by including measures under more than one program. Rather, we believe including a measure in more than one program and aligning the measures specifications signals CMS' desire for better performance in that area and serves to increase the motivation for such improved performance. While we

agree with the principle of alignment across a variety of programs, it is beyond the purview of this program to align fully with external programs or to explain differences between our measurement set and the numerous other measurement sets in existence. However, our final measurement set is aligned with the National Quality Strategy. In response to the commenters that recommended we make public our overall quality measurement strategy, we agree that it is important that we make our quality strategy publicly available and have done so through our Web site and a large number of public events.

Final Decision: We will finalize our proposal to align the Shared Savings Program quality measures reporting requirements with those in other programs, to the extent possible, as previously discussed.

G. Shared Savings and Losses

1. Authority For and Selection of Shared Savings/Losses Model

Section 1899 of the Act, as added by section 3022 of the Affordable Care 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.'' However, section 1899(d)(1)(A) of the Act also provides for an ACO to receive payment for shared Medicare savings provided that the ACO meets both the quality performance standards established by the Secretary, as discussed in section II.F. of this final rule, and demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures. Additionally, section 1899(i) 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. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

In the November 17, 2010 **Federal Register**, we solicited public comment on a number of issues regarding ACOs and the Shared Savings Program, including the types of additional payment models we should consider in addition to the model laid out in section 1899(d) of the Act, either under the authority provided in section 1899(i) of the Act or using the Innovation Center authority under section 1115A of the Act. We further asked about the relative advantages and disadvantages of any such alternative payment models.

In the proposed rule, we described and sought comment on several options for structuring the Shared Savings Program. One option we considered was to offer a pure one-sided shared savings approach using the calculation and payment methodology under section 1899(d) of the Act. This option 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. Another reason we considered this option was that a one-sided model with no downside performance risk might be more accessible and attract smaller group participation. However, as some RFI commenters suggested, while such a model may provide incentive for participants to improve quality, it may not be enough of an incentive for participants to improve the efficiency and cost of health care delivery. Therefore, we considered a second option to use our authority under section 1899(i) of the Act to create a performance risk-based option in the Shared Savings Program. Such a model would have the advantage of providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides greater reward for greater responsibility.

Another approach we considered would be to offer a hybrid approach. A hybrid approach would combine many of the elements of the one-sided model under section 1899(d) of the Act with a performance risk-based approach under section 1899(i) of the Act.

Based on the input of commenters on the November 17, 2010 RFI, other stakeholders and policy experts we proposed to implement a hybrid approach. Specifically, we proposed that ACOs participating in the Shared Savings Program would have an option between two tracks:

Track 1: Under Track 1, shared savings would be reconciled annually for the first 2 years of the 3-year agreement using a one-sided shared savings approach, with ACOs not being responsible for any portion of the losses above the expenditure target. However, for the third year of the 3-year agreement, we proposed to use our authority under section 1899(i) of the Act to establish an alternative two-sided payment model. Under this model, an ACO would be required to agree to share losses generated as well as savings. ACOs that enter the Shared Savings Program under Track 1 would be automatically transitioned to the two-sided model in the third year of their agreement period. In that year, the ACO's payments would be reconciled as if it was in the first year of the two-sided model. However, quality scoring would still be based on the methods for the third year (that is, it would not revert back to the first year standard of full and accurate reporting). Thereafter, those ACOs that wish to continue participating in the Shared Savings Program would only have the option of participating in Track 2, that is, under the two-sided model. As proposed, we envisioned that this track would provide an entry point for organizations with less experience with risk models, such as some physician driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model.

Track 2: More experienced ACOs that are ready to share in losses with greater opportunity for reward could elect to immediately enter the two-sided model). An ACO participating in Track 2 would be under the two-sided model for all 3 years of its agreement period. Under this model, the ACO would be eligible for higher sharing rates than would be available under the one-sided model. We proposed that this track 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 general, we proposed the same eligibility requirements and methodologies for the two tracks. That is, we proposed to use 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, and transparency requirements for ACOs under the one-sided and two-sided models. We also explained our belief that the proposed monitoring procedures in combination with our proposed use of a retrospective beneficiary assignment methodology and proposed beneficiary notification requirements were sufficient to guard against the prospects that two-sided model ACOs might try to avoid at-risk beneficiaries in order to minimize the possibilities of realizing losses against

their benchmarks. However, we invited comments on the sufficiency of the proposed monitoring procedures as well as additional areas and mechanisms for monitoring two-sided model ACOs.

We proposed adding some requirements to the program in order to provide further assurance about the ability of an ACO operating under the two-sided model to repay the Medicare program in the event of incurred losses. We proposed requiring all ACOs to demonstrate, as part of their application and in advance of entering the two-sided model, the establishment of a repayment mechanism to ensure repayment of losses to the Medicare program. We stated our belief that the proposed eligibility requirements for ACOs in addition to the requirement that ACOs demonstrate an adequate repayment mechanism were sufficient to ensure the ability of ACOs to repay CMS in the event they incur losses. We sought comment on whether additional eligibility requirements were necessary for ensuring that ACOs entering the two-sided model would be capable of repaying CMS if actual expenditures exceeded their benchmark.

Further, we proposed to provide greater financial incentives to ACOs that participate under the program's two-sided model to encourage ACOs to enter the two-sided model, which we believe has a greater potential than the one-sided model to induce meaningful and systematic change in providers' and suppliers' behavior.

In the proposed rule, we described our intention to design and test partial capitation models in the Innovation Center first in order to gain more experience with such models, introduce them to providers of services and suppliers, and refine them, before applying them more widely in the Shared Savings Program.

Comment: Many comments indicated general support for our proposal to base the Shared Savings Program on a framework of existing FFS payments. However, some commenters urged CMS not to confine its payment method to the current, traditional Medicare fee-for-service payments to ACO participants but instead to employ a variety of alternative payment approaches. In some cases, commenters recommended these alternatives to facilitate participation by specific provider types or the inclusion of specific types of services. One commenter suggested this is necessary to ensure the success of the program. Another commenter, generally, supported testing of various payment and care delivery models through the Innovation Center.

Of those who recommended alternative payment models, commenters most commonly recommended inclusion of the following payment models in the Shared Savings Program: blended fee-for-service payments; prospective payments; episode/case rate payments; bundled payments; patient-centered medical homes and surgical homes payment models; payments based on global budgets; full capitation; partial capitation such as condition-specific capitation; and enhanced FFS payments for care management, such as care coordination fees. Several others suggested CMS allow ACOs to use incentives to ensure beneficiaries adhere to treatment regimens or seek care within the ACO.

In the case of enhanced FFS payments, commenters offered a variety of suggestions on the form for such payments. Most commonly, commenters suggested CMS pay for physicians' consultative or coordination services provided via e-mail or telephone, such as self-management support for patients with chronic diseases, or through a per-member per-month (PMPM) care management fee (for example, in the range of $10–$50 PMPM). One commenter offered a specific proposal for incorporating enhanced FFS payments. Specifically, CMS should use its authority under section 1899(i) of the Act to authorize payment for CPT codes for telephone calls and other non-face-to-face services used by ACOs that accept downside risk to improve care management and hold ACOs accountable for repaying a portion of these payments should they bill for these codes but fail to achieve savings. CMS should then collect data on the impact of paying for these services to determine if this payment policy should be expanded to FFS Medicare. Another suggested example would be for CMS to authorize payment for telemedicine codes reported by ACOs. Another commenter suggested using a budget neutral way to provide these payments by reallocating dollars from inpatient and specialty reimbursement.

Some commenters recommended CMS offer other targeted payment models to facilitate participation by certain types of ACOs, such as small physician-only ACOs, and ACO participants, namely small- and medium-sized physician practices, especially those in rural areas; or to support care for particular types of patients, such as dual eligible beneficiaries.

Several comments related to the overall design of the proposed program. One commenter suggested the Shared Savings Program is an overly complex approach to cost management and urged CMS to find a simpler solution. The commenter suggested setting expenditure benchmarks relative to geographic areas, allowing ACOs that meet quality thresholds to keep FFS payments received, and penalizing ACOs that do not reduce expenditures. Another commenter suggested allowing ACOs to share in first dollar savings for all Medicare beneficiaries seen by the ACO, not just those assigned to the ACO. A third commenter urged CMS to ensure a consistent approach and level playing field as between the Shared Savings Program and Medicare Advantage.

Response: We appreciate commenters' interest in and support for adopting other payment models in the Shared Savings Program, but disagree with suggestions that CMS use its authority under section 1899(i) of the Act to include additional alternative payment models in the program at this time. We believe many of the suggested payment models remain untested. We are concerned that immediately adopting models on a national scale with which we have no experience could lead to unintended consequences. However, as discussed in section II.B.6. of this final rule, it is the Innovation Center's task to test novel payment models under its demonstration authority. We anticipate that as we gain experience through the Innovation Center with novel payment models what we learn could be more widely adopted in the Shared Savings Program. We would note that a number of commenters expressed support for testing alternative models through the Innovation Center.

Comment: Several comments reflected confusion about the proposed payment model under the Shared Savings Program. For instance, some commenters asserted that the program will, in fact, make partial capitation payments, or questioned if providers electing not to participate in the program will continue to receive payment as usual.

Response: We would like to clarify that consistent with section 1899(d)(1)(A) of the Act, fee-for-service providers will continue to receive payments ''under the original Medicare fee-for-service program under Parts A and B in the same manner as they would otherwise be made'' regardless of whether they participate in the Shared Savings Program. Also, as indicated previously, we do not plan to adopt partial capitation (or other such payment methodologies) at this time, but may do so in the future through

appropriate rule-making, depending on lessons learned through demonstrations.

Comment: A few commenters noted concerns that uncertainty about the Sustainable Growth Rate (SGR) for FY 2012 could undermine the program, as doctors could be subject to lower reimbursement rates and also be potentially subject to shared losses under the Shared Savings Program. One commenter suggested that CMS delay publication of the final rule for the Shared Savings Program until clarification of the FY 2012 SGR. Further, one commenter suggested that physician reimbursement rates are already too low to cover costs, and the ''flawed'' SGR formula needs to be addressed to allow physicians to adapt new care delivery models. Another commenter suggested that the SGR and the Shared Savings Program are redundant mechanisms to control utilization and focus on prevention, quality and efficiency, and as such CMS should develop a process for waiving SGR requirements for physicians participating in ACOs.

Response: We decline to use our authority under section 1899(f) of the Act to waive the requirements of the SGR methodology for ACO participants as it is not necessary to waive these requirements in order to carry out the provisions of section 1899 and implement the Shared Savings Program. Rather, the statute at section 1899(d)(1)(A) expressly provides that we continue to make payments to the providers and suppliers participating in an ACO ''* * * in the same manner as they would otherwise be made * * *.'' Accordingly, addressing concerns about the SGR methodology is beyond the scope of this rule for the Shared Savings Program. We note, however, the publication of the proposed rule for the 2012 Medicare Physician Fee Schedule on July 1, 2011, and the publication of the final rule, to include the Secretary's initial estimate of the SGR for 2012, later this year.

Comment: The comments reflected a variety of opinions on the proposed two track approach. Several commenters supported retaining the proposed two track approach in the final rule. As one commenter explained, a shared savings only track may be appropriate for newly formed organizations to gain experience with accountable care models, but a model that includes shared performance-based risk is necessary to drive meaningful change. A few commenters strongly favored the proposal to transition ACOs under the one-sided model to a shared savings and risk model in the third year while offering more mature ACOs the option to enter into a shared savings and risk model in the first year; indicating the importance of shared performance-based risk in the delivery transformation necessary to achieve the three-part aim and for ''good stewardship'' of Medicare Trust Fund dollars.

However, most commenters expressed concerns with requiring ACOs to quickly accept performance risk for the costs of their patients, or even to accept risk at all, and suggested this proposal could diminish participation. Several comments noted that for organizations (particularly small- and medium-sized practices) that do not have any experience with care management or managing performance-based risk, a shared savings only option would better enable them to feel comfortable making the significant investments necessary to transition to the accountable care model. Along these lines, commenters suggested that including a shared savings only model would encourage participation by certain groups, such as: small- and medium-sized physician practices, loosely formed physician networks, safety net providers, small ACOs, and rural ACOs.

Some commenters expressed reservations about the proposed inclusion of the two-sided model. Some commenters were concerned that a downside risk payment model could jeopardize the financial health of ACOs and may ultimately result in market dynamics similar to those precipitating the managed care backlash in the 1990s; although, several commenters noted the additional proposed program protections would safeguard against these problems. One commenter cautioned that absent sufficient care coordination systems, blame for losses might lie with certain groups of physicians (such as emergency medicine physicians). Another commenter explained that risk emphasizes financial outcomes over patient-centered care. Further, several commenters questioned the authority for including shared losses in the program. For example, commenters suggested that Congress intended only a shared savings program, or expressed concern that a requirement for ACOs to repay shared losses would constitute an unlicensed quota share reinsurance arrangement.

Commenters offered the following specific reasons for why ACOs entering Track 1 should not automatically transition to the two-sided model in their third performance year:

- Insufficient time exists for ACOs to gain necessary experience with population management to generate savings prior to being required to accept risk.
- The risk for substantial loss already exists for new ACOs because of the unknowns about the potential for ACOs to generate savings given the significant upfront investments needed to build ACO infrastructure and the anticipated high operational costs.
- Potential ACOs may lack access to Medicare claims data that would enable them to evaluate the nature or magnitude of the downside risks they would be accepting.
- When beneficiaries retain freedom to see any provider and when assignment is retrospective, Medicare ACOs may lack the ability to have certainty over identification of their assigned population and even when identified, there is a possibility for significant turnover or lack of cooperation with an ACO's efforts to control expenditures.
- The proposed cap on risk adjustment may increase ACO risk for losses or reduced savings.
- The potential for increased costs that are beyond the ACO's control exists.
- Risk may incent ACOs to cherry pick patients, for example, by excluding from the ACO physicians which treat high cost patients.

Hence, commenters suggested a variety of alternatives to our proposal, for example, that we—

- Establish a one-sided, shared savings only track—the most commonly made recommendation.
- Remove the two-sided model as an option for ACOs.
- Remove the one-sided model as an option for ACOs.
- Extend the length of time available in a one-sided shared savings model by extending an agreement period or allowing ACOs to participate in a one-sided model for additional performance years or agreement periods.
- Exempt some ACOs from downside risk, such as small, rural and physician-only ACOs. For instance, extend an exemption from the two-sided model to those ACOs exempted from the 2 percent net sharing requirement, or develop additional tracks tailored for smaller medical practices or rural providers and suppliers. Other commenters suggested exempting ACOs in low cost States and those in areas where high hospital readmission rates result from a lack of access to community-based services beyond the ACO's control.
- Make the ACO's population the determinant of the applicable model, for instance, beneficiaries with high cost

conditions would be under the one-sided model and the remainder of the beneficiary population would be under two-sided model.

• Develop a 4-tiered approach to hold organizations at different stages of development to different standards.

However, some patient advocate groups generally cautioned against amending policies to make the program more attractive to providers at the expense of clinical or financial benefits which could accrue from ACOs.

Response: We believe that maintaining a two track approach is important for attracting broad participation, including providers and suppliers new to value-based purchasing and more experienced ACOs that are ready to share in losses. Commenters supported our belief that models where ACOs bear a degree of financial risk hold the potential to induce more meaningful systematic change, which underscores the importance of transitioning ACOs from the one-sided model to risk-based arrangements. However, the commenters also persuaded us that ACOs new to the accountable care model—and particularly small, rural, safety net, and physician-only ACOs—would benefit from additional time under the one-sided model before being required to accept risk. Commenters persuaded us further that revising Track 1 to be a shared savings only option, while retaining Track 2 as a shared savings/losses model, would be the most appropriate means to achieve this objective. Accordingly, we will finalize our proposal to offer the two-sided model under Track 2 to ACOs willing and able to take on performance-based risk in exchange for higher reward, but will offer Track 1 as a shared savings only track for the duration of the first agreement period for ACOs needing more experience before taking on risk. We believe this modification will 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 for greater reward immediately. However, we continue to believe that models that hold a degree of financial risk have the potential to induce more meaningful changes. As such, an ACO will be eligible for no more than one agreement period under the shared savings only model.

We were also encouraged by commenters' interest in including alternative payment models in the Shared Savings Program. As indicated in the proposed rule, it is our intent to gain experience with several alternative payment models through the Innovation Center before potentially adopting them more widely in the Shared Savings Program.

Comment: We received a few comments on the alignment of the one- and two-sided models on 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, and transparency requirements. Several commenters suggested that retrospective assignment could be particularly problematic for ACOs under the two-sided model, expressing concern that ACOs would be accountable for losses from assigned beneficiaries whom they could not identify and whose care they could not influence.

Response: Unless stated otherwise elsewhere in this final rule, we decline to further differentiate the program's two models on the basis of 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, and transparency requirements for ACOs because we believe the policies being adopted in this final rule are appropriate for all ACOs, regardless of whether they are participating in a one-sided or two-sided model. In addition, we believe that the preliminary prospective assignment methodology that we are adopting in this final rule will sufficiently address commenters' concerns about the ability of an ACO to identify its potential assigned beneficiaries in order to allow for effective care management.

Accordingly, we are finalizing our proposal to offer ACOs a choice of two tracks, but modify our proposal for Track 1. Track 1 will be a shared savings only model (under the one-sided model) for the duration of the ACO's first agreement period. We will make final our proposal that ACOs electing Track 2 will be under the two-sided model for the duration of their first agreement period.

In the proposed rule we discussed several options about how to incorporate a two-sided model into the Shared Savings Program. The major options we considered were—

• Base the program on a two-sided model, thereby requiring all participants to accept risk from the first program year.

• Allow applicants to choose between program tracks, either a one-sided model or two-sided model, for the duration of the agreement.

• Allow a choice of tracks, but require ACOs electing the one-sided model to transition to the two-sided model during their initial agreement period.

We explained that requiring all ACOs to initially take downside risk would likely inhibit the participation of some interested entities, particularly organizations which lack the experience and capital to accept significant downside risk. We further explained that allowing ACOs to choose from either a one-sided model or a two-sided model created concerns, in particular that ACOs capable of taking risk could take advantage of the option that allows for gain by realizing savings without any risk for incurring added costs. In the proposed rule, we stated that we believed it is important that all Shared Savings Program participants quickly move to taking on downside risk because payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in providers' and suppliers' behavior. We further explained our belief that, by introducing a risk model, we could elicit applicants to the program who are more serious about their commitment to achieving the program's goals around accountability for the care of Medicare beneficiaries and the three-part aim of enhancing the quality of health care, improving patient satisfaction with their care, and better controlling the growth in health care costs.

We proposed that applicants would have the option of choosing between a one-sided model and a two-sided model initially. Under Track 1, ACOs enter the program under the one-sided model and must transition to the two-sided model for the third year of their initial agreement period. Alternatively, under Track 2, an ACO may enter the two-sided model option immediately for a full 3-year agreement period. We further proposed that all ACOs, whether participating under Track 1 or Track 2, must participate in the two-sided model in subsequent agreement periods. Thus, under our proposal, an ACO could only participate for a maximum of 2 years under the one-sided model, during its first agreement period, before it must transition and participate thereafter in the Shared Savings Program under the two-sided model. We stated our belief that this approach would allow ACOs to gain experience with the accountable care model under the one-sided model, while also encouraging organizations to take on greater risk with the opportunity for greater reward by migrating them to the two-sided model. We invited

comment on this proposal and other options for incorporating a two-sided model into the Shared Savings Program, including mechanisms for transitioning ACOs to two-sided risk arrangements.

Comment: Some commenters urged CMS to allow ACOs to accept risk on a voluntary basis, ''at their own pace.'' MedPAC, among others, favored extending the time an ACO could participate under the one-sided model, but to ultimately require ACOs to accept downside risk. Those favoring transition to the two-sided model suggested it provides greater incentives for ACOs to eliminate unnecessary expenditures and improve integration and care coordination. The most common suggestion was to allow ACOs to participate under the one-sided model for an initial 3 year agreement period and thereafter require ACOs to accept risk. Others suggested extending the availability of the one-sided model to ACOs beyond the first agreement period, with suggestions ranging from 4, 5, or 6 years. Some commenters suggested allowing certain types of ACOs additional time under the one-sided model, such as small, rural and physician-only ACOs; for instance expanding the proposed exemption of these organizations from a 2 percent net sharing rate to the requirement to transition to the two-sided model. One commenter suggested making the one-sided model available only to early adopters. A hybrid approach would be to allow ACOs two agreement periods under the one-sided model with the option to voluntarily switch to the two-sided model at the beginning of any calendar year.

Other commenters recommended alternatives for transitioning Track 1 ACOs to risk in their third year, but exempting them from repaying some or all of their losses. For instance, one commenter suggested holding Track 1 ACOs harmless for the first 2 percent of losses in year 3 if they generated savings in their first two performance years, based on the idea that our compensation through the proposed 2 percent net sharing requirement for the one-sided model. Alternatively, this commenter suggested, more generally, using savings generated in a prior performance year to off-set the amount of losses owed.

Several commenters were concerned that an automatic transition to risk would result in ACOs under the two-sided model that lacked the capacity to bear risk. One commenter recommended a more measured approach, whereby CMS would evaluate an ACO's readiness to assume risk before transitioning it to the two-sided model. Commenters suggested various options for ACOs unable to accept risk at the point of required transition to the two-sided model: Termination by CMS, voluntarily withdrawal, and completion of the agreement period under the one-sided model with no opportunity to continue in the program.

Response: Earlier in this section, we specify that in this final rule we are adopting a final policy under which ACOs will have a choice of two tracks for their first agreement period: a shared savings only model (Track 1) or the two-sided model (Track 2). However, we are finalizing our proposal to require an ACO to participate under the two-sided model after its initial agreement period. We continue to believe that accountability for losses is an important motivator for providers to change their behavior and to maximize reductions in unnecessary expenditures, and that the prospect of accountability for losses will ensure that the program attracts participants that take seriously their commitment to achieving the program's goals.

We appreciate commenters' concerns about a mandatory transition to risk and their recommendations to allow ACOs to voluntarily assume risk. Because ACOs will be required to enter the two-sided model only in subsequent agreement periods, ACOs will have the option to decide whether to continue to participate. As a result, those ACOs that decide to continue participating in the program at the end of their first agreement period will be voluntarily entering the two-sided model. In selecting the length of time an ACO could remain under the one-sided model, we found support in comments for limiting the period to the first agreement period. Further, as discussed later in this final rule, we are revising our proposed policy in order to allow ACOs that have a net loss during their first agreement period to continue to participate in the program, provided they meet all other participation requirements. We believe that this policy provides further support for limiting participation under the one-sided model to an ACO's initial agreement period. Underperforming ACOs would be allowed to continue in the Shared Savings Program, but all ACOs that elect to do so would be required to be accountable for their losses. Lastly, we disagree with commenters' suggestions that we exempt some ACOs entirely from the two-sided model, or otherwise allow ACOs to participate in the one-sided model for an extended or indefinite period of time. Absent a limit on participation under the one-sided model we anticipate that ACOs capable of taking on risk would take advantage of the option that allows for gain by realizing savings without any risk for incurring losses by remaining in the one-sided model.

We appreciate commenters' concerns about the transition of ACOs to the two-sided model when they lack the financial reserves necessary to safely assume risk. We believe the repayment mechanism in this final rule, is sufficient to safeguard against ACOs entering the two-sided model when they lack the capacity to bear risk.

Additionally, we proposed that an ACO may not reapply to participate in the Shared Savings Program if it previously experienced a net loss during its first agreement period. We explained that this proposed policy would ensure that under-performing organizations would not get a second chance. We sought comment on this proposal and whether denying participation to ACOs that previously underperformed would create disincentives for the formation of ACOs, particularly among smaller entities.

Comment: Commenters expressed concern about the proposal to disallow continued participation by financially under-performing ACOs. Commenters suggested this policy could serve as a disincentive to participation, particularly by small ACOs. They believed organizations may be reluctant to make the necessary investments to form ACOs given the uncertainty over their ability to produce shared savings during the initial agreement period and their ability to continue in the program beyond 3 years. Some commenters suggested it may take several years for an ACO to demonstrate shared savings, indicating that some well-intentioned ACOs may not be able to do so by the end of their initial agreement period. Several commenters suggested eliminating the proposed policy. Others suggested adopting a more flexible approach to avoid penalizing well-meaning ACOs, such as:

- Allowing continued participation for ACOs that, despite experiencing a net loss, demonstrate a consistent decrease in the net loss over the initial 3 years of the agreement.
- Judging ACOs' readiness to continue in the program based on quality, not cost, performance. For instance, allow continued participation for ACOs which meet the program's quality performance requirements.

Response: We are modifying our proposal to allow continued participation by ACOs electing to do so who experience a net loss during their first agreement period. We recognize that it may take longer than the term of

an ACO's initial agreement period for an ACO to achieve shared savings, particularly ACOs new to the accountable care model. Commenters have persuaded us that barring ACOs that demonstrate a net loss from continuing in the program could serve as a disincentive for ACO formation given the anticipated high startup and operational costs of ACOs. Our policies on monitoring and termination will help to ensure that ACOs that underperform on the quality standards do not continue in the program. Further, continued participation by previously underperforming ACOs could benefit the Trust Funds– as compared to FFS providers not engaged in the Shared Savings Program—as these ACOs will participate under the two-sided model and therefore will have an even greater incentive to improve the quality and efficiency of the care they provide in order to avoid being accountable for shared losses. While there appear to be a number of benefits to allowing financially underperforming ACOs to continue to participate in the program, we believe this policy could be cause for concern, as it may allow ongoing participation by organizations that are not dedicated to the accomplishment of the program's goals but that reap the benefits from participation, such as legal protections under the waivers. Therefore we are further requiring ACOs which experience a net loss in their initial agreement period, applying to participate in a subsequent agreement period, to identify in their application the cause(s) for the net loss and to specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. Further, we will monitor closely this aspect of the program, and may revise our policy in future rulemaking.

We are modifying our proposal to allow an ACO which experiences a net loss during its first agreement period to reapply to participate in the Shared Savings Program.

Final Decision: As provided in § 425.600, we will establish the Shared Savings Program on existing FFS payments, using both shared savings only (Track 1) and shared savings and losses models (Track 2). While making final our proposal to offer ACOs a choice of two tracks, we are modifying our proposal for Track 1 so that it will be a shared savings only model for the duration of the ACO's first agreement period. We will make final our proposal that ACOs electing Track 2 will be under the two-sided model for the duration of their first agreement period. We are also finalizing our proposal to require all ACOs to participate in the two-sided model in agreement periods subsequent to the initial agreement period. We are modifying our proposal to allow continued participation by ACOs electing to do so who experience a net loss during their first agreement period. Specifically, we are requiring ACOs, which experience a net loss in their initial agreement period and apply to participate in a subsequent agreement period, to identify in their application the cause(s) for the net loss and to specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. Further, we will monitor closely this aspect of the program, and may revise our policy future rulemaking.

2. Shared Savings and Losses Determination

a. Overview of Shared Savings and Losses Determination

We proposed that the shared savings model (one-sided model) and a shared savings/losses model (two-sided model) would share many program elements in common, including a similar methodology for determining whether an ACO has achieved savings against the benchmark. Unless specifically noted, the elements discussed in the rest of this section will apply to both the one-sided and two-sided models. However, we also explained the necessity to develop some policies for the two-sided model that would not be necessary under a one-sided model, including, for example, a methodology for determining shared losses. The following table provides an overview of our final decisions on elements of the program's financial models.

TABLE 5—SHARED SAVINGS PROGRAM OVERVIEW

	One-sided model		Two-sided model	
Issue	Proposed	Final	Proposed	Final
Transition to Two-Sided Model.	Transition in third year of first agreement period.	First agreement period under one-sided model. Subsequent agreement periods under two-sided model.	Not Applicable	Not Applicable.
Benchmark	Option 1 reset at the start of each agreement period.	Finalizing proposal	Option 1 reset at the start of each agreement period.	Finalizing proposal.
Adjustments for health status and demographic changes.	Benchmark expenditures adjusted based on CMS–HCC model.	Historical benchmark expenditures adjusted based on CMS–HCC model. Performance year: Newly assigned beneficiaries adjusted using CMS–HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS–HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year.	Benchmark expenditures adjusted based on CMS–HCC model.	Historical benchmark expenditures adjusted based on CMS–HCC model. Performance year: Newly assigned beneficiaries adjusted using CMS–HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS–HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year.
Adjustments for IME and DSH.	Include IME and DSH payments.	IME and DSH excluded from benchmark and performance expenditures.	Include IME and DSH payments.	IME and DSH excluded from benchmark and performance expenditures.

TABLE 5—SHARED SAVINGS PROGRAM OVERVIEW—Continued

	One-sided model		Two-sided model	
Issue	Proposed	Final	Proposed	Final
Payments outside Part A and B claims excluded from benchmark and performance year expenditures;	Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals.	Finalize proposal	Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals.	Finalize proposal.
Other adjustments	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments.	Finalize proposal	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments.	Finalize proposal.
Maximum Sharing Rate	Up to 52.5 percent based on the maximum quality score plus incentives for FQHC/RHC participation.	Up to 50 percent based on the maximum quality score.	Up to 65 percent based on the maximum quality score plus incentives for FQHC/RHC participation.	Up to 60 percent based on the maximum quality score.
Quality Sharing Rate	Up to 50 percent based on quality performance.	Finalizing proposal	Up to 60 percent based on quality performance.	Finalizing proposal.
Participation Incentives	Up to 2.5 percentage points for inclusion of FQHCs and RHCs.	No additional incentives	Up to 5 percentage points for inclusion of FQHCs and RHCs.	No additional incentives.
Minimum Savings Rate	2.0 percent to 3.9 percent depending on number of assigned beneficiaries.	Finalizing proposal based on number of assigned beneficiaries.	Flat 2 percent	Finalizing proposal: Flat 2 percent.
Minimum Loss Rate	2.0 percent	Shared losses removed from Track 1.	2.0 percent	Finalizing proposal.
Performance Payment Limit.	7.5 percent	10 percent	10 percent	15 percent.
Performance payment withhold.	25 percent	No withhold	25 percent	No withhold.
Shared Savings	Sharing above 2 percent threshold once MSR is exceeded.	First dollar sharing once MSR is met or exceeded.	First dollar sharing once MSR is exceeded.	First dollar sharing once MSR is met or exceeded.
Shared Loss Rate	One minus final sharing rate.	Shared losses removed from Track 1.	One minus final sharing rate.	One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate not to exceed 60 percent.
Loss Sharing Limit	5 percent in first risk bearing year (year 3).	Shared losses removed from Track 1.	Limit on the amount of losses to be shared phased in over 3 years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the annual limit would not be shared.	Finalizing proposal.

The basic requirements for establishing and updating the benchmark, as well as determining whether an ACO has achieved savings against the benchmark, are outlined in section 1899(d)(1)(B) of the Act. Section 1899(d)(1)(B)(i) of the Act establishes that an ACO shall be eligible for payment of shared savings ''only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark * * *.'' Consistent with the statute, we proposed to take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including payments made under a demonstration, pilot or time limited program when computing average per capita Medicare expenditures under the ACO. The statute further requires the Secretary to establish the percentage that expenditures must be below the applicable benchmark ''to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.'' We will refer to

this percentage as the ''minimum savings rate'' (MSR).

Section 1899(d)(1)(B)(ii) of the Act requires the Secretary to establish and update the ''* * * benchmark for each agreement period for each ACO 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 section also requires the benchmark to ''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 service program, as estimated by the Secretary.'' A new benchmark is to be established consistent with these requirements at the beginning of each new agreement period.

Section 1899(d)(2) of the Act provides that, if the ACO meets the quality performance standards established by the Secretary, as discussed in section II.F. of this final rule ''a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this title.'' We will refer to this percentage as the ''sharing rate.'' This section also requires the Secretary to ''establish limits on the total amount of shared savings that may be paid to an ACO.'' We will refer to this limit as the ''sharing cap''.

Thus, in order to implement the provisions of section 1899(d) of the Act for determining and appropriately sharing savings, we must make a number of determinations about the specific design of the shared savings methodology described by the statute.

First, we must establish an expenditure benchmark, which involves determining: (1) The patient population for whom the benchmark is calculated; (2) appropriate adjustments for beneficiary characteristics such as demographic factors and/or health status that should be taken into account in the benchmark; (3) whether any other adjustments to the 3-year benchmark are warranted, so as to provide a level playing field for all participants; and (4) appropriate methods for trending the 3-year benchmark forward to the start of the agreement period, and subsequently for updating the benchmark for each performance year during the term of the agreement with the ACO.

Second, we must compare the benchmark to the assigned beneficiary per capita Medicare expenditures in each performance year during the term of the agreement in order to determine the amount of any savings.

Third, we must establish the appropriate MSR, as required by the statute ''to account for normal variation in expenditures… based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO'' and we must determine the appropriate sharing rate for ACOs that have realized savings against the benchmark and meeting or exceeding the MSR.

Finally, we must determine the required sharing cap on the total amount of shared savings that may be paid to an ACO. We discuss all these issues, and our final policies for addressing them, in this section.

In light of the greater potential for a two-sided model to bring about positive changes in the operation of the FFS system by improving both the quality and efficiency of medical practice, we believe that it is appropriate to provide greater incentives for organizations that participate in the two-sided model. For example, as we described in the proposed rule, we believe that it is appropriate to provide a higher sharing rate for organizations participating in the Shared Savings Program under the two-sided model than for those organizations participating under the one-sided model.

In addition to a methodology for determining shared savings, the two-sided model requires a methodology for determining shared losses in those cases where an ACO realizes a loss as opposed to a savings against its benchmark in any performance year. We proposed to mirror the structure and features of the shared savings methodology as much as possible in the determination of loss sharing. As discussed later in this final rule, for purposes of the loss-sharing methodology, we proposed adopting a similar structure of minimum loss rate (the equivalent of minimum savings rate on the savings side), shared loss limit, and loss sharing rate.

We address the methodological steps for determining shared savings and losses, related comments, responses, and our final policy decisions, in the sections discussed later in this final rule.

Comment: We received a wide range of comments requesting or suggesting adjustments to specific policies so that an ACO could share in a higher level of savings or lower amount of losses than what was proposed. Generally, commenters expressed the view that the reward to risk ratio for participating in the program as proposed is unattractive to providers, and commenters favored policies that would attract broad participation by providers. Commenters explained that financial rewards must be sufficient to offset provider risks and startup-costs. According to one commenter ''the program as envisioned under the proposed rule places inordinate investment pressure on medical providers for an insufficient return that carries a significant amount of risk, regardless of the type of ACO.'' Comments reflected concern that this pressure is increased for small ACOs, such as those comprised largely of small and medium sized physician practices; small hospitals and safety net providers, particularly those serving rural areas; and providers serving high risk patients (for example, dual eligibles and oncology patients). Commenters suggested that participation in the proposed program will be effectively limited to those few large entities already organized under an ACO-like structure; entities that already have ready access to capital, substantial infrastructure development, and experience operating under an integrated service/payment model (for example, MA). Even entities which might meet these criteria questioned the ''business case'' for adoption of the ACO model as outlined in the proposed rule. Further, some commenters expressed concern that the cost of ACO formation may foster the development of large health system-based or hospital-based ACOs thereby financially undermining small, independent physician practices.

Several commenters questioned the adequacy of the program's incentives for primary care physicians, on which the program focuses. These commenters highlighted primary care physicians' critical role in coordinating care across care settings from the home to the hospital and ensuring that beneficiaries see the appropriate specialists. They indicated that primary care physicians will have to incur additional costs for case management and coordination of patient care to achieve the program's goals with what will be a potentially insufficient and uncertain incentive—the chance that there will be a cost savings disbursed to them. Further, commenters suggested that to the extent these physicians experience financial failure as a result of assuming risk, the program could exacerbate the primary care physician shortage, for example by discouraging physicians from specializing in primary care practice.

Typically, recommendations we received for improving the value

proposition of program participation included the following:

- Revise the methodology for establishing the benchmark to encourage participation by organizations that are already efficient or in low cost areas.
- Risk adjust expenditures with the CMS–HCC model during both the benchmark and performance periods to account for changes in acuity and movement in the assigned beneficiary population.
- Standardize the benchmark and performance year expenditures by excluding payments made in pursuit of policy goals, such as IME and DSH payments.
- Make it easier for ACOs that perform well on quality to receive savings, by increasing the sharing rate based on quality performance and reducing or eliminating the MSR and the 2 percent net sharing requirement.
- Allow ACOs to receive a larger share of savings achieved by lowering or eliminating the 25 percent payment withhold and performance payment limit.
- Include a non-risk option, so that ACOs may participate under a shared savings-only model while they gain experience with the accountable care model.

Commenters' specific concerns about particular aspects of the shared savings and losses methodology are further detailed in this section of this final rule.

Response: Commenters' arguments persuaded us of the need to improve the financial attractiveness of the program to encourage broad participation by providers and suppliers, particularly those likely to comprise smaller ACOs, such as small and medium sized physician practices, rural and safety net providers. One particularly compelling argument suggested that allowing ACOs to receive a greater share of savings would support ongoing investment in and achievement of the program's goals. Further, we agree with commenters' suggestions on the need to adjust policies related to determining shared savings/losses to avoid unintended consequences for certain groups of beneficiaries and providers or suppliers. For instance, updating ACOs' risk scores to better reflect changes in their assigned populations could remove incentives for ACOs to avoid beneficiaries with high cost or complex conditions. Excluding IME and DSH payments may allay concerns that inclusion of these payments could incent ACOs to avoid certain types of providers, such as Academic Medical Centers. Accordingly, as described in the later sections of this final rule, we are revising several of our proposed policies to make the program, overall, more financially rewarding to ACOs, to better adjust for changes in assigned beneficiaries' health status, and to ensure ACOs include providers and suppliers that can provide the high quality care for Medicare beneficiaries. Underlying our decisions regarding the policies we are adopting in this final rule is the need to address the (sometimes competing) interests of ACOs, beneficiaries, the Medicare Trust Funds, and the goal of achieving the intended transformative effects. We believe the financial models presented in the final rule offer an appropriate balance of payment incentives, while still furthering the purpose and intent of the program.

b. Establishing the Benchmark

Section 1899(d)(1)(B)(ii) of the Act specifies several requirements with regard to establishing an ACO's benchmark. These requirements are as follows:

- First, the law requires the Secretary ''to estimate a benchmark for each agreement period for each ACO 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.''
- Second, the law requires that ''[s]uch benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate.''
- Third, the law requires that the benchmark be ''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.''
- Finally, the law requires that ''[s]uch benchmark shall be reset at the start of each agreement period.''

In the proposed rule, we considered two legally permissible approaches to implementing the statutory language for estimating the benchmark, which we called Option 1 and Option 2. Both approaches involved benchmarks derived from prior expenditures of assigned beneficiaries and adjusted for certain beneficiary characteristics, and other factors, the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures. Under both approaches, we proposed to reset the benchmark at the start of each agreement period. However, a key difference between these two approaches was the beneficiary population used to determine expenditures for purposes of the benchmark. Specifically, under Option 1, we proposed estimating an ACO's benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in each of the 3 years prior to the start of an ACO's agreement period using the ACO participants' TINs. As such, this methodology would generate benchmark expenditures based on the average population cared for by the ACO participants during the preceding 3 years. In contrast, under Option 2, we proposed basing the benchmark on the Parts A and B FFS expenditures of individual beneficiaries assigned to the ACO during each performance year, with the benchmark expenditures being those incurred in the 3 years immediately preceding the ACO's agreement period for each of those assigned beneficiaries. Under both Option 1 and Option 2, the benchmark would be reset (or rebased) the start of each agreement period. In the proposed rule, we proposed to adopt Option 1 to establish each ACO's benchmark; however, we solicited comments on both options. For a detailed description of Options 1 and 2, please see our April 7, 2011 proposed rule (76 FR 19604 through 19606).

Comment: We received numerous comments related to our proposal to base the benchmark on an ACO's own past cost experience. One commenter commended us for establishing the benchmark based on an ACO's historical per capita expenditures. This commenter noted that a similar approach has proven successful in a private sector value based purchasing initiative, and that this methodology offers important confidence to groups that the starting budgets represent a fair and appropriate allocation of resources.

The majority of comments, however, expressed concern with our proposal to establish the benchmark based on ACOs' historical per capita expenditures, regardless of whether Option 1 or Option 2 was implemented. In most cases, commenters expressed concern that the proposed benchmarking methodology would disadvantage efficient providers or those in low-spending areas and reward poor performers in high cost areas. Thus, commenters suggested that efficient organizations may be less willing to participate in the program because they have already invested in the systems and infrastructure to produce high-quality, low cost care, and will have difficulty achieving additional efficiencies, and hence savings, given the proposed benchmark methodology. In particular, some commenters suggested the proposed policy would

deter participation by rural providers, asserting they already operate at or near the lowest cost possible. Another commenter suggested that providers operating in the Indian Health System may have difficulty reaching savings requirements and other benchmarks because of the current funding and delivery system structure. One commenter suggested that further cost control in already efficient areas may lead to undesirable results, including, for example, limited ACO interest in participation or reduced beneficiary access to needed care. However, one commenter suggested effort will be needed by providers in both higher cost and lower cost areas to reduce costs, and it may not necessarily be 'easier' for providers in higher cost markets to achieve this transformation.

Relative to their concerns, as an alternative, some commenters suggested that CMS exercise its authority under section 1899(i) of the Act to develop and implement an alternative benchmarking methodology. Commenters suggested alternatives such as using local, regional or national experience to establish the ACOs' benchmarks; however, opinions varied as to which approach among these would be most appropriate. Some commenters suggested a blended approach based on local and national spending, for instance use of a combination of local and national averages or a phased approach to transition from initial use of local averages to a national average over time.

Other suggestions for establishing the initial benchmark included applying alternatives including the following:

- A prospective benchmark based on burden of illness with bonus payments that reflect quality care through better clinical and patient-reported outcomes.
- A peer-to-peer benchmarking methodology. For instance, one commenter suggested that existing high cost ACOs should be required to achieve a higher percentage of improvement in order to share in savings while ACOs with historically lower costs should be rewarded for smaller improvements over the threshold.
- A matched cohort of Medicare fee-for-service beneficiaries as a basis for comparison for those beneficiaries being treated under an ACO.
- A fixed percentage of total operating funds for all ACO providers, such as 85 percent of geographic-adjusted expenditure per capita. The difference between this benchmark and the medical loss ratio incurred by any ACO would be shared savings.
- Methodologies specifically for ACOs in low-cost regions, such that these ACOs would have the opportunity to earn greater rewards.
- A menu of benchmarking methodologies from which the organization can choose, similar to the methodology used in the Hospital Value-Based Purchasing program.
- A rolling 3 year look-back.
- A benchmark established by determining which beneficiaries would have been assigned to the ACO, determining their actual utilization during the relevant 3-year period, and re-pricing the cost of those services using the ACO's fee schedule for the relevant performance year being compared.

Response: We understand concerns raised by commenters on basing benchmarks on ACO's historical per capita expenditures. Section 1899(d)(1)(B)(ii) of the Act is clear, however, that ''The Secretary shall estimate a benchmark for each agreement period for each ACO 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.'' Thus, consistent with statute, we plan to make final our proposal to establish ACO benchmarks 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.

Comment: As mentioned previously, very few comments addressed the specific methodology that we should use for establishing ACO benchmarks—that is, Option 1 or Option 2—although a few commenters, including MedPAC, suggested CMS adopt a benchmarking methodology similar or identical to that proposed for the Innovation Center's Pioneer Model ACOs, which tends to align with Option 2. For instance, MedPAC, among others, recommended calculating ACOs' benchmarks based on expenditures of individual beneficiaries assigned to the ACO. A number of commenters raised concerns about the accuracy of the benchmark and performance year expenditures in circumstances when we have only partial data for an assigned beneficiary—issues that would more typically occur under Option 2 than Option 1. For instance, several commenters suggested that using Option 2 would require an additional adjustment to account for beneficiaries who cross over to or from another payer, such as Medicaid or Medicare Advantage, and to account for decedents and beneficiaries treated in an institutional setting where their costs may not be attributable to an ACO under the proposed assignment methodology. Moreover, when adjusting expenditures for decedents, commenters tended to oppose the methods we discussed under Option 2 for adjusting for decedents, specifically the method of excluding the expenditures of deceased beneficiaries from actual expenditures during the agreement period. Several commenters suggested that while excluding these expenditure data would protect ACOs from catastrophic costs incurred in the patient's last year of life, it would have unintended consequences such as discouraging better end of life care management, and one commenter suggested CMS consider a method to risk adjust for expected costs in a beneficiary's final year of life. Another commenter favored the second method we discussed under Option 2: Comparing average expenditures for each deceased beneficiary during the agreement year to the average expenditures for beneficiaries included in the benchmark. Under this option, we would make no adjustment if the agreement year expenditures were 5 percent or less above the benchmark, but would make adjustments if expenditures were greater than 5 percent above the benchmark.

Response: On balance, we believe Option 1 is the most appropriate approach for establishing ACO benchmarks for at least initial use in the program, and plan to make final this proposal. We believe Option 1 establishes a statistically stable benchmarking methodology based on the ACO's average population by which we can assess improvements the ACO makes in the quality and efficiency of care delivery for its average population. We also acknowledge there are drawbacks to this benchmark methodology, including that it provides incentives for ACOs to seek and/or avoid specific beneficiaries during the agreement period so that their average expenditures would likely be less than for their historical beneficiaries included in the benchmark. For this reason we favor a benchmarking methodology based on an ACO's actual assigned population, such as Option 2, MedPAC's suggested approach, or as proposed for Pioneer Model ACOs. However, we lack experience with this model of benchmarking and the related need to adjust for decedents, sudden increases in individual costs, and incomplete expenditure data on some assigned beneficiaries. We support the Innovation Center's testing of this benchmarking approach through the Pioneer Model ACO initiative, and look forward to applying lessons learned from the Pioneer experience towards

developing a robust benchmarking methodology for possible use within the Shared Savings Program. We intend to revisit use of a benchmarking methodology based on the ACO's assigned population in future rule making, as soon as practicable, once we gain more experience with this benchmarking approach through the Pioneer Model.

Comment: Some commenters expressed concerns that the proposed assignment methodology would exclude some of Medicare FFS beneficiaries' costs from the ACOs' benchmark and thereby disadvantage certain providers and the populations they serve. One commenter expressed concern that assignment of beneficiaries based on primary care services rendered by physicians with primary care specializations could exclude beneficiaries with disabilities and those needing medical rehabilitation services which rely on care by specialists. This commenter favored a step-wise approach to assignment in which beneficiaries are assigned first on the basis of care by primary care physicians followed by a second ''sweep'' of assignment based on specialists would help ensure that these beneficiaries' costs would be counted.

Many commenters expressed concern that Medicare FFS beneficiaries treated by FQHCs and RHCs would not be assigned to an ACO or have their costs reflected in an ACO's benchmark under the proposed assignment and benchmarking methodologies. A commenter stated: ''The statute does not appear to require the specific methodology that has been proposed by CMS to determine the benchmark, and certainly does not require a single uniform methodology for all primary care providers. Under the wording of this provision, CMS appears to have the flexibility to apply a methodology to 'estimate a benchmark' specifically for FQHCs.'' This commenter and some others suggested various ways to compute the benchmark for FQHCs absent 3 years of benchmark data: (1) CMS could use the data and claims it will have from FQHCs for 2011 and assume similar and comparable data and claims for the two years prior with some adjustments as appropriate relating to inflation, etc.; (2) CMS could assign beneficiaries utilizing the 2011 data and recover billing data from the prior 2 years with use of health center office visit revenue codes to determine the 3 year benchmark; (3) CMS could further investigate the methods that are being used to create benchmarks for demonstrations, such as the methods that were considered for the Pioneer ACO Model Request for Applications; (4) a number of FQHCs have been recording HCPCS codes for all of their patients and have this information stored in their practice management systems, dating back prior to the requirement to report to CMS starting on January 1, 2011. Those centers that are able to provide CMS with the data it requires to establish the 3-year benchmark should be allowed to do so; and (5) CMS could allow each health center to voluntarily choose whether it would provide any specific requested information. Further, commenters suggested that section 1899(i), if not section 1899(d) of the Act, provides CMS flexibility to estimate a benchmark specifically for FQHCs.

One commenter advocated allowing those RHCs and FQHCs who wish to participate in ACOs the opportunity to provide the requisite data so that they may fully participate in the program. However, another commenter appreciated the Department's reluctance to impose reporting requirements in this rule for both FQHCs and RHCs and other entities without either a statutory requirement or clear support for such a regulatory change from the community at large.

Response: In the section II.E. of this final rule, we establish a step-wise approach to beneficiary assignment that simultaneously maintains the primary care-centric approach to assignment and recognizes the necessary and appropriate role of specialists in providing primary care services. Through this assignment methodology we will be able to attribute to ACOs expenditures for beneficiaries who predominantly rely on care from specialists.

Based on the assignment process that we are adopting in this final rule (see section II.E. of this final rule), we are able to compute a benchmark for ACOs that include FQHCs and RHCs, in the same manner as we would for any other ACO. For ACOs that consist of FQHCs and/or RHCs (either independently or in partnership with other eligible entities), we will establish such ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of an ACO's agreement period.

Comment: As described in section II.G. of this final rule, several commenters recommended that we trend and update the benchmark and risk adjust by categories of beneficiaries, including aged, disabled and ESRD beneficiaries, among others.

Response: We agree with commenters' suggestions for taking a categorical approach to establishing the benchmark and are adopting this approach for calculating expenditures for the historical benchmark. In this final rule, we are adopting a policy whereby the historical benchmark expenditures will be calculated for cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries. We will sort beneficiaries according to these categories in the order in which they are stated. We will make a distinction between the aged/dual eligible and aged/non-dual eligible populations since modeling has suggested the expected expenditures for these populations is significantly different. The ESRD and disabled categories include both dual eligible and non-dual eligible beneficiaries, however, since modeling has indicated expenditures are less divergent for these populations. As described in section II.G. of this final rule, we are adopting this categorical approach to establishing the benchmark, updating the benchmark and calculating performance year expenditures.

Comment: We received a number of comments on our proposal to minimize variation from catastrophically large claims by truncating an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for each benchmark year and performance year. Mostly commenters were supportive of the proposal to adjust for outliers. Some commenters suggested that the proposed limitations may provide ACOs inadequate protections from high-cost beneficiaries, and suggested a variety of additional or alternate limitations including the following:

- Remove outliers altogether from the assigned populations used to establish the benchmark and performance year expenditures. For instance, one commenter suggested excluding all costs incurred by patients with rare and extreme diagnoses or for care received in the tertiary care setting, while another recommended CMS use in the Shared Savings Program an approach similar to what was proposed for the Pioneer Model ACOs, in which ACOs have the option to exclude from benchmark and performance year expenditures claims above the 99th percentile for national per capita expenditures.
- Reduce the outlier threshold from the 99th percentile to the 75th or 95th percentile, for instance, to help ensure

that ACOs are not penalized for using innovative technologies.

• Use a flat dollar amount, such as $100,000 per year, instead of a percentile as a basis for truncating claims.

• Use ''alternate windsoring techniques'' for adjusting a distribution for outliers; for example, calculating separate savings among different cost categories of beneficiaries, such as the top 5 percent of beneficiaries by cost versus the remaining 95 percent of beneficiaries.

• Exclude claims for high cost treatments demanded by the patient that have a negative result, in part as a means of addressing higher medical costs in States with high rates of medical malpractice litigation.

One commenter expressed concern that under the proposed policy, ACOs would have little incentive to effectively coordinate care for high cost beneficiaries. This commenter explained that the proposed policy may negatively impact dialysis patients because these patients' costs may be close to the 99th percentile threshold. If an ACO knows its risk exposure is limited for what may be a small portion of its assigned population, such as ESRD beneficiaries, the ACO may have little incentive to spend time and money needed to provide high quality care to these beneficiaries.

Several commenters asked for clarification about the proposed truncation methodology, including whether the same 99th percentile will be applied to the benchmark or performance year expenditures or if it will be determined within each performance year. Several commenters asked for clarification as to whether the expenditure amount includes hospital outlier payments, or otherwise how outlier payments to inpatient facilities will be handled. One commenter asked generally how CMS will ensure providers with high cost patients are able to receive savings.

Response: We are finalizing our proposal to truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark year and performance year. We disagree with those commenters that suggested placing greater limitations on ACOs' accountability for the cost of outliers, such as by completely removing outliers from ACO benchmark and performance year expenditures or lowering the threshold (such as the 95th percentile). Doing so would give ACOs less incentive to coordinate care and services for high-cost beneficiaries, for whom improved care coordination could be especially valuable, to improve outcomes and control unnecessary costs.

The 99th percentile represents a dollar amount (roughly $100,000) that matches in dollar terms an attachment point that is fairly common in the reinsurance market. The important reason for its inclusion is that it reduces variation in expenditure growth, thereby lowering the risk of paying ACOs savings or requiring ACOs to pay losses that result from random variation. A lower percentile might have been chosen, but the incremental benefit in terms of lowered variation would be offset by further reduction in the incentive for ACOs to increase efficiency for high-cost patients. Therefore, we believe that truncating claims at the 99th percentile achieves an appropriate balance between limiting catastrophic costs and continuing to hold ACOs accountable for those costs that are likely to be within their control.

We appreciate commenters' concerns that by limiting ACO's accountability for catastrophic costs, ACOs may have an incentive to avoid managing the care for the select few very high-cost beneficiaries. However, we believe that truncating claims at the 99th percentile in conjunction with the opportunity to receive shared savings, as well as monitoring protections, help assure ACOs will not avoid treating at-risk beneficiaries. We also note, in response to the commenter who expressed concern that an ACO could not achieve savings for high cost beneficiaries, that one of the purposes of risk adjustment is to make it possible for ACOs that improve the quality and efficiency of the care they provide to achieve savings in the cost of care for both high and low cost beneficiaries.

Accordingly, as specified in the proposed rule, we will truncate all Parts A and B FFS per capita expenditures at the 99th percentile for each beneficiary in each benchmark year and for each assigned beneficiary in each performance year. Further, we will truncate for outliers in the ACO's assigned population as opposed to accounting for outlier payments made to hospitals (potential ACO participants) which will be included in the calculation of actual expenditures during the performance year.

Comment: Several comments generally suggested that the proposed policy for weighting benchmark expenditures at 60 percent for BY3, 30 percent for BY2 and 10 percent for BY1 was appropriate. Several others recommended alternative approaches to weighting benchmark expenditures. For instance, one commenter recommended that CMS weight the most expensive benchmark year the highest, followed by the second highest and finally the least expensive. Another commenter suggested, relative to Option 2 for establishing the benchmark, to weight BY3 at 60 percent and BY2 at 40 percent.

Response: We thank the commenters for their support of our proposed policy. We continue to believe that our proposed approach to weighting base year expenditures, compared to the alternatives suggested by commenters, will result in a more accurate benchmark. This approach recognizes that the ACO's financial performance in the most recent base year is the most current of the three base years and therefore reflects more accurately the latest expenditures and health status of the ACO's assigned beneficiary population. Further, weighting BY1 at zero, as suggested by one commenter, would not meet the statutory requirement under section 1899(d)(1)(B)(ii) of the Act to establish the benchmark using the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. Accordingly, we are finalizing our proposal to weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent.

Comment: Many commenters urged CMS not to reset the benchmark for ACOs that continue in the program after the first agreement period, or to limit how far the baseline could be moved from one agreement period to the next. They indicated that rebasing the benchmark each agreement period will make savings more difficult to attain and eventually make savings unattainable. They further suggested this could discourage initial participation in the program, as organizations will have little incentive to make the needed investment in ACO formation. Commenters recommended a number of alternatives to mitigate these anticipated effects which included the following:

• Never rebasing.

• Delayed rebasing, for example apply the original baseline for longer than 3 years, such as 6 or 9 years (covering a second and third agreement period).

• Apply partial, as opposed to full, rebasing.

• Rewarding ACOs for maintaining, rather than further decreasing, their expenditures.

• Using rebasing as a mechanism to facilitate ACOs' transition from FFS to capitated payments.

On the other hand, several commenters favored resetting the benchmark more frequently than we proposed, stating their preference for a rolling 3 year look back to reset the ACO's benchmark annually.

Further, some commenters provided technical suggestions on how to reset the benchmark. One commenter suggested that we take inflation into consideration when resetting the benchmark as to not penalize ACOs for market increases beyond their control. Another commenter suggested that reset benchmarks must include payments for care management and coordination services and urged CMS to establish rates that ACOs could bill for such services. This commenter further suggested that such rates should vary based on the beneficiary's number of chronic conditions and the acuity of these conditions (such as severe mental illness and/or chemical dependence), as well as socio-economic or environmental risk factors that would require additional social services.

Response: We are finalizing our proposal to reset the benchmark at the start of each agreement period, as required under section 1899(d)(1)(B)(ii) of the Act. Moreover, we believe that resetting the benchmark at the beginning of each agreement period will most accurately account for changes in an ACO's beneficiary population over time. As we indicated in the proposed rule, turnover in assigned beneficiaries could be approximately 25 percent year to year. By the end of the agreement period, an ACO's assigned population may be significantly different from the historically assigned beneficiary population used to calculate the ACO's initial benchmark. Resetting the benchmark at the beginning of subsequent agreement periods will allow the benchmark to more accurately reflect the composition of an ACO's population, and therefore will protect both the Trust Funds and ACOs. We appreciate commenters' concerns that resetting the benchmark after 3 years could ultimately make it more challenging for ACOs to achieve savings, particularly for low-cost ACOs; however, we believe that one of the fundamental purposes of the Shared Savings Program is to provide incentives for ACOs to strive continually to make further advances in the quality and efficiency of the care they provide. We also appreciate commenters' technical suggestions on resetting the benchmark in relation to beneficiary health status, and socio-economic and environmental factors. While at this time we decline to use authority under section 1899(i) of the Act to adopt an alternate approach to resetting the benchmark, we may reconsider the issue in future rulemaking.

Final Decision: We are making final our proposed methodology under § 425.602 for establishing an ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of an ACO's agreement period using the ACO participants' TINs identified at the start of the agreement period. We will calculate benchmark expenditures by categorizing beneficiaries in the following cost categories, in the order in which they appear: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This benchmarking methodology will apply to all ACOs, including those consisting of FQHCs and/or RHCs (either independently or in partnership with other eligible entities). We are also making final our proposals to truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark and performance year; weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent; and reset the benchmark at the start of each agreement period. Further, as specified in section II.C. of this final rule, we will use a 3-month run-out of claims data and a completion factor to calculate benchmark expenditures.

c. Adjusting the Benchmark and Actual Expenditures

(1) Adjusting Benchmark and Performance Year Average per Capita Expenditures for Beneficiary Characteristics

Section 1899(d)(1)(B)(i) of the Act stipulates that an ACO is eligible for shared savings ''only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services, adjusted for beneficiary characteristics'' is below the applicable benchmark. Likewise, section 1899(d)(1)(B)(ii) of the Act specifies that the benchmark ''shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate * * *'' This requirement to adjust for ''beneficiary characteristics'' implicitly recognizes that, under a shared savings model, the realization of savings against a benchmark could be a function of two factors. One factor is reduced expenditure growth as a result of greater quality and efficiency in the delivery of health care services. The other factor could be changes in the characteristics of the beneficiaries who are under the care of the ACO. Thus, in the absence of risk adjustment, some organizations may realize savings merely because they are treating a patient mix with better health status than the patient population reflected in their benchmark. On the other hand, some organizations may share in savings on a risk adjusted basis that would not have shared in savings if expenditures were not risk adjusted.

When applying a risk adjustment model, it is necessary to guard against changes that result from more specific or comprehensive coding as opposed to improvements in the coordination and quality of health care. An ACO's ability to share in savings can be affected not only by changes in the health status of the ACO's assigned population but also by changes in coding intensity and changes in the mix of specialists and other providers within an ACO, which in turn could affect the characteristics of its assigned beneficiary population, relative to the benchmark period. As we stated in the proposed rule, our goal is to measure improvements in care delivery of an ACO and to make appropriate adjustments to reflect the health status of assigned patients as well as changes in the ACO's organizational structure that could affect the case mix of assigned patients rather than apparent changes arising from the manner in which ACO providers/suppliers code diagnoses.

To address these concerns, in the proposed rule, we considered 3 options for risk adjusting the initial benchmark. One option was to employ a method that considered only patient demographic factors, such as age, sex, Medicaid status, and the basis for Medicare entitlement (that is, age, disability or ESRD), without incorporating diagnostic information. The second option was to employ a methodology that incorporates diagnostic information, in addition to demographic variables, specifically the CMS–HCC prospective risk adjustment model that has been used under the Medicare Advantage (MA) program. The third option was to implement the MA ''new enrollee'' demographic risk adjustment model: a model that includes adjustments for age, sex, Medicaid enrollment status, and

originally disabled status, but would not take into account the health status of the assigned beneficiaries.

We proposed to adjust Medicare expenditure amounts using the CMS–HCC model because it more accurately predicts health care expenditures than the demographic-only model as it accounts for variation in case complexity and severity. We also noted that incorporating diagnosis data in the risk adjustment model would encourage ACOs to code more fully or intensely for purposes of population management and quality reporting, and to optimize their risk scores to achieve shared savings. We elected not to propose the MA new enrollee model because it could have an adverse effect on ACOs that include providers and suppliers that typically treat a comparatively sick beneficiary population, including academic medical centers and tertiary care centers.

We also considered, and sought comment on, several approaches to account for the upward trend in risk scores which may result from coding changes alone, without improved methods of beneficiary care, such as the following:

- Use of normalization factors and coding intensity adjustments, as is done for the MA program.
- Use of an annual cap in the amount of risk score growth we would allow for each ACO. For instance, we considered setting a fixed growth percentage for all ACOs and negating any risk score growth over the cap. Alternatively, we could establish a risk score for the ACO's assigned population during the agreement period based on the calculated risk score of beneficiaries who were used to calculate the ACO's benchmark.
- Use of a methodology similar to the MA methodology that would reduce the amount of growth in the risk scores for beneficiaries assigned to ACOs, but continue to allow increases.

We further explained our expectation that the ACO's average population risk scores would remain stable over time, given that there is expected to be stability in ACO participants and therefore case mix and we will have calculated the benchmark risk adjustment score for the ACO's historically assigned beneficiary population under conditions when the ACO providers/suppliers would not have had the same incentive to increase coding. We stated that we considered the benchmark risk adjustment score for the ACO's historically assigned beneficiary population to be a reasonable approximation of the actual risk score for the beneficiary population assigned to the ACO during the agreement period, while avoiding any distortion due to changes in coding practices. Therefore, we proposed a cap of zero percent growth on risk adjustment by calculating a single benchmark risk score for each ACO and applying this same risk score throughout the agreement period to the annual assigned patient population's per capita expenditures for assigned beneficiaries.

We specified our intent to monitor and evaluate the issue of more complete and accurate coding as we gained experience with the Shared Savings Program, and that we would consider making revisions and adaptations to the final risk adjustment model through future rulemaking if warranted. Further, to assure the appropriateness of ACO coding practices and our methodology for risk adjusting, we proposed to retain the option to audit ACOs, especially those ACOs with high levels of risk score growth relative to their peers, and to adjust the risk scores used for purposes of establishing the 3-year benchmark accordingly. We sought comment on these proposals.

Comment: Commenters typically expressed support for adjusting benchmark expenditures based on the CMS–HCC model; although, some commenters raised technical concerns about the accuracy of HCC risk adjustment. For example, one commenter suggested that CMS needs to improve the accuracy of the HCC risk adjustment model. Other commenters expressed concern that the proposed risk adjuster lacks the capacity to account for socioeconomic status. Another commenter suggested the need for physician input into risk adjustment factors, for example, to be able to identify patients with multiple chronic conditions. Commenters also made a number of recommendations about the proposed risk adjustment methodology, including the need to define other ''beneficiary characteristics'' that might be used to risk adjust, modify the HCC model to exclude zero spend beneficiaries (while these beneficiaries are included in the HCC model as used in MA, it could disadvantage ACOs whose assigned populations would by definition exclude zero spend beneficiaries), and risk adjust for including safety net providers, such as RHCs, FQHCs and Method I CAHs.

While commenters supported use of the CMS–HCC model for adjusting benchmark expenditures, they also expressed concern that benchmark and performance expenditures would not also be annually updated for risk using this same mechanism. Numerous commenters expressed concern that a cap on risk adjustment in cases where care furnished to a patient is documented and appropriate would diminish the level of shared savings, and serve as a disincentive to manage patients with complex health care needs who can most benefit from better care coordination. MedPAC, among other commenters, expressed concern that this approach would create incentives for ACO providers to encourage existing patients who are costly to seek care elsewhere and to avoid taking on new patients that could be costly. Another commenter suggested that accurate risk adjustment is especially important for providers, such as academic medical centers, that disproportionately treat the sickest and most complex patients.

Some commenters were concerned that the proposed cap on risk adjustment would not adequately capture changing severity of disease in the ACO's assigned population. For example, one commenter encouraged CMS to allow for timely and appropriate risk adjustment for cancer patients, particularly to address the circumstance under which a patient has not been diagnosed with cancer when the benchmark is set, but is later diagnosed with and treated for cancer. Another commenter noted that individuals with multiple health conditions will still need more services than other beneficiaries with lower acuity. Another commenter expressed concern that the proposed risk adjustment methodology would not account for changes in beneficiaries' health status which result from aging.

Others were concerned that the proposed cap on risk adjustment would not address changes in the ACO's population as beneficiaries move to different providers during the agreement period. For instance, some commenters pointed to our experience with the PGP demonstration, which showed approximately a 25 percent variation in assignment from year to year. One commenter suggested, based on its own experience in the demonstration, that the turnover rate may be higher.

Accordingly, several commenters encouraged CMS to adopt policies that would encourage ACOs to care for high-risk and high-cost beneficiaries. The alternative most often recommended by commenters is for CMS to annually update performance expenditures for risk. In their view, these annual updates would help keep pace with a changing patient population, for example in terms of beneficiary age, acuity or severity of health status and movement of beneficiaries into and out of the ACO's assigned patient population. As one

commenter recommended, the ACO's risk adjustment score should be determined by the population the ACO is actually treating, and should therefore be recalculated for each year of the agreement period. This commenter further suggested that the potential for, and presumably consequences of, increased coding intensity are far outweighed by concerns about creating incentives to avoid complex patients or penalizing institutions that treat patients in their performance period who are more complex compared to their benchmark population. One commenter noted the importance of adjusting the ACO's benchmark for changes in risk scores during the agreement period, indicating that doing so could limit incentives for ACOs to avoid high-cost and high-risk beneficiaries.

Among the alternatives offered by comments, some commenters recommended a narrower approach, suggesting that CMS annually update ACOs' risk scores for select populations of beneficiaries, such as the aged, disabled and ESRD populations, and beneficiaries with chronic disease codes, or create exceptions for safety net providers. One commenter suggested CMS apply a cap of 10 percent on any annual increase in risk scores, based on coding severity, unless an ACO can provide a satisfactory sampling of assigned beneficiaries audited to support the use of proper coding and therefore higher risk adjustments. Another commenter recommended that risk adjustment be made retrospectively, on an annual basis, based on the ACO's assigned patients.

A number of commenters specifically addressed the relationship between coding accuracy and coding intensity. One commenter viewed the concept of coding intensity as synonymous with coding accuracy. Several commenters suggested that improvements in coding will likely occur over time as a result of ACO formation, for example, as more providers adopt EHR and can code more completely. One commenter pointed out that this improvement in coding should be viewed positively, and suggested that the issue of disproportionate relative risk growth for a subpopulation due only to improved coding accuracy will self-correct. One commenter encouraged CMS to educate physicians and other providers in preparation for the implementation of ICD–10 in 2013, which could result in a significant change in coding. Another commenter noted their agreement with the proposal to address coding accuracy by the proposed audit process.

Commenters suggested a number of alternatives to mitigate the effects of increased coding intensity which included the following:

- Adjust for increased coding intensity as is done for the MA program.
- Do not subject new enrollees or those transitioning from MA to the risk score change limitations.
- Allow ACOs to request a one-time benchmark recalculation during the agreement period.

One commenter suggested CMS investigate, on an ongoing basis, risk adjustment methods that could capture the unexplained variation in spending or risk of a population.

Response: We continue to believe that risk adjusting benchmark expenditures based on the CMS–HCC model accounts for variation in case complexity and severity and therefore more accurately predicts health care expenditures compared to a demographic-only model or other alternatives suggested by commenters. We did not intend for our proposed risk adjustment methodology to discourage ACOs from accepting responsibility for beneficiaries that might present higher than average risk, but commenters have persuaded us of the need to better account for risk associated with changes in the ACO's beneficiary population, for instance in terms of acuity and beneficiary movement, during the agreement period. However, we remain concerned that liberally adjusting for changes in risk scores for beneficiaries assigned to the ACO for the entire agreement period could create an incentive for ACOs to use coding practices intended to optimize their risk scores to achieve shared savings. Thus, we are modifying our initial proposal so that ACO benchmarks will better reflect the risk associated with their assigned beneficiaries. We will adjust expenditures to account for changes in severity and case mix for beneficiaries newly assigned in the current performance year (''newly assigned''), and those who are continuously assigned to the ACO year-to-year (''continuously assigned''). A newly assigned beneficiary is a beneficiary assigned in the current performance year who was neither assigned nor received a primary care service from any of the ACO's participants during the most recent prior calendar year. A continuously assigned beneficiary is 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's participant during the most recent prior calendar year.

First, for newly assigned beneficiaries we will annually update an ACO's CMS–HCC prospective risk scores to adjust for changes in severity and case mix in this population. Second, each year, we will recalculate the ACO's CMS–HCC prospective risk scores for continuously assigned beneficiaries. If the continuously assigned population shows a decline in its CMS–HCC prospective risk scores, we will adjust for health status changes for this population using this lower risk score. If the continuously assigned population shows no decline, this population will be adjusted using demographic factors only. We believe that this approach to risk adjustment strikes a fair balance between accounting for changes in the health status of an ACO's population while not incenting changes in coding practices for care provided to beneficiaries who remain continuously assigned to the ACO, nor encouraging ACOs to avoid high risk beneficiaries. This methodology implicitly adjusts for beneficiaries who are assigned in the prior year but not the current performance year (patients which leave the ACO), as these beneficiaries will be excluded from the continuously assigned population. We will monitor HCC scores for beneficiaries which are assigned in the prior year who are not assigned in the current performance year, to determine if there is trend in changes in health status for this population. Based on our findings, in future rule making, we may make a more explicit adjustment for beneficiaries assigned to the ACO in the prior year who are not assigned in the current performance year. Further, we agree with the commenter's suggestion on the need for benchmark expenditures to be adjusted relative to the risk profile of the performance year assigned beneficiaries. Therefore the ACO's updated benchmark will be restated in the appropriate performance year risk to ensure fairness recognizing changes in the level of risk among the ACO's assigned beneficiaries.

Additionally, we agree with commenters' suggestions about the need to take account of variations in risk scores across categories of beneficiaries to reflect differences in disease severity across subpopulations. Therefore, in adjusting for health status and demographic changes, we will make adjustments for separate categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid

beneficiaries as described in section II.G.2.b. of this final rule.

Also, we agree with the comment recommending that we use the audit process to address coding inaccuracies. Therefore, to assure the appropriateness of ACO coding practices and our methodology for risk adjusting, we are finalizing our proposal to retain the option to audit ACOs, especially those ACOs with high levels or risk score growth relative to their peers, and to adjust the risk scores used for purposes of establishing the 3-year benchmark accordingly. In addition, as we stated in the proposed rule, we intend to monitor and evaluate the issue of more complete and accurate coding and, as we gain experience with the program, we may consider making further revisions through future rulemaking.

Final Decision: We are making final our proposal under § 425.602 to risk adjust an ACO's historical benchmark expenditures using the CMS–HCC model. We are modifying our proposal under § 425.604 and § 425.606 to make additional risk adjustments to performance year assigned beneficiaries instead of capping growth in risk adjustments during the term of the agreement at zero percent. For newly assigned beneficiaries, we will annually update an ACO's CMS–HCC prospective risk scores, to take into account changes in severity and case mix for this population. We will use demographic factors to adjust for severity and case mix for the continuously assigned population relative to the historical benchmark. However, if the continuously assigned population shows a decline in its CMS–HCC prospective risk scores, we will lower the risk score for this population. An ACO's updated benchmark will be restated in the appropriate performance year risk relative to the risk profile of the performance year assigned beneficiaries. Further, we will make adjustments for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. We are also making final our proposal to monitor and evaluate the issue of more complete and accurate coding for future rule making and to use an audit process to assure the appropriateness of ACO coding practices and to adjust ACO risk scores. We will also monitor HCC scores for beneficiaries assigned in the prior year that are not assigned in the current performance year, and may make a more explicit adjustment for this population in future rule making.

(2) Technical Adjustments to the Benchmark and Performance Year Expenditures

Consistent with the statute, we proposed to take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including payments made under a demonstration, pilot or time limited program when computing average per capita Medicare expenditures for an ACO during both the benchmark period and performance years.

In the proposed rule, we stated our belief that all relevant Medicare costs should be included in an ACO's benchmark to maintain sufficient incentives for ACOs to ensure their assigned beneficiaries receive care in the most appropriate settings. We noted that payment adjustments achieve policy goals such as supporting teaching hospitals and hospitals that serve a disproportionate share of low income beneficiaries, adjusting for local wage differences, or accounting for providers' performance on quality initiatives. We further explained that adjustments to payment rates can affect both expenditures during the benchmark period and also during each subsequent performance year. Additionally, changes in these payment factors, between the benchmark and performance years could also influence whether an ACO realizes savings or incurs losses under the program.

In the proposed rule, we addressed the issue of whether to exclude some adjustments to Parts A and B payments when determining ACOs' benchmark and performance year expenditures. We considered a number of specific claims-based payment adjustments in the proposed rule, including: IME and DSH payments, geographic payment adjustments, and some bonus payments and penalties. We also discussed some payment adjustments which are outside the payments for Parts A and B services and therefore would not be included in our calculation of ACOs' expenditures.

We explained that section 1899(d) of the Act provides a way of adjusting for such payments in the benchmark. Section 1899(d)(1)(B)(ii) of the Act states, among other things, that the benchmark must be adjusted for "* * * beneficiary characteristics and such other factors as the Secretary determines appropriate * * *." However, when it comes to performance year expenditures, section 1899(d)(1)(B)(i) of the Act provides authority to adjust expenditures in the performance period for beneficiary characteristics, but does not provide authority to adjust for "other factors." Therefore, we noted that while we could make some adjustments to the benchmark, to exclude certain payments, we could not make similar adjustments in our calculation of performance year expenditures. We did not discuss the possible use of our authority under section 1899(i) of the Act, which authorizes use of other payment models, to adjust performance year expenditures for "other factors."

Comment: We received a number of comments on adjusting for payments and policies not mentioned in the proposed rule. Commenters requested clarification, or made recommendations, on the treatment of a number of payments or costs. Among these, commenters recommended that we exclude the following:

- Costs of preventive services from an ACO's benchmark and spending calculations to avoid incentives to withhold preventive care.
- Costs of urgent care center visits from ACO's benchmark and performance year expenditures to avoid creating incentives for ACOs to refer their non-emergent patients to their own emergency departments instead of to urgent care centers in the community.
- Costs of beneficiaries who seek care outside the ACO.
- New technology payments under the Inpatient Prospective Payment System and transitional pass through payment expenditures under the Outpatient Prospective Payment System for drugs, biological and devices. Commenters believed exclusion of these payments would avoid incentives for ACOs to underuse new technologies and therapies. One commenter, for example, suggested that CMS' exclusions keep pace with the latest recommended treatments.
- Rural health payment adjustments under which CMS reimburses some providers under alternative, specialized methodologies due to their designation as rural or critical access facilities.
- Low cost county payments.
- Primary care incentive payments under the primary care incentive program established by the Affordable Care Act.
- Federal hospital insurance trust fund payments.
- TEFRA relief payments, the inclusion of which could provide incentives for ACOs to avoid forming joint ventures with and including cancer centers.

Commenters offered differing opinions on the treatment of Part D costs. One commenter urged us to include Part D costs, suggesting this could maximize ACO's opportunity for success because of the opportunities for

cost savings and improved quality associated with drug benefits. Several commenters expressed concern that in some clinical areas (such as cancer care and cardiac ablation for atrial fibrillation) ACOs may have an incentive to move patients from appropriate treatments or procedures reimbursed through Parts A or B to Part D therapies which are excluded from the shared savings calculation. Commenters suggested safeguards may be needed for certain clinical areas. One commenter outlined a process for CMS to exclude the costs of certain Part A and B drugs/biologics or medical procedures from the shared savings calculation, but to account for use of Part D drugs as an alternative to procedures paid under Parts A and B. One commenter identified a seemingly countervailing effect resulting from the proposed additional incentive for ACOs to include FQHCs and RHCs, which may be entities eligible for the 340B Drug Pricing Program. The commenter explained that the incentive for including FQHCs and RHCs may prompt ACOs to shift treatment protocols and patients from an inpatient setting to an outpatient setting in order to have access to 340B pricing discounts.

Several commenters expressed the need for CMS to take into consideration payment policies and causes for payment changes which could affect ACO financial performance. One commenter noted that some payment rules can run counter to the goals of the Shared Savings Program, for instance post-acute care transfer policies that reduce payments if the beneficiary is moved to certain other types of providers prior to reaching the geometric mean average length of stay for that diagnosis-related group. ACOs will be mindful these types of payment adjustments, which could result in higher Medicare spending. This commenter suggested the need to align payment policies to be consistent with the goals of the Shared Savings Program, and recommended that CMS not apply payment policies that penalize providers for directing the setting of care. Several other commenters suggested that we consider adjustments to the benchmark and performance year expenditures to account for changes in the structure of ACO providers and suppliers which may have a significant impact on annual payment rates, such as a hospital receiving the status of ''sole community provider,'' or a hospital incorporating a provider-based billing clinic that was previously freestanding. Another commenter suggested CMS develop a method to account for the defensive practice of medicine which results in higher medical costs, particularly in States with higher rates of medical malpractice litigation.

One commenter recommended that CMS offer a process where individual ACOs could petition for specific benchmark adjustments that might be relevant to their providers or beneficiaries, but would not be relevant to all ACOs.

As described section II.G. of this final rule, several commenters recommended that we trend and update the benchmark and risk adjust by categories of beneficiaries, including aged, disabled, and ESRD beneficiaries, among others.

Response: We disagree with commenters' suggestions that we adjust ACO benchmark and performance year expenditures to account for various differences in cost and payment among providers and suppliers. We believe 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. Similarly, 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 Fund 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 therapies and unintended shifts in the site of care for beneficiaries with high cost therapies, we believe that the program's quality measurement and program monitoring activities will help us to prevent and detect any avoidance of appropriately treating at-risk beneficiaries. Furthermore to the extent that these lower cost therapies are not the most appropriate and lead to subsequent visits or hospitalizations 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.

As we indicated in the discussion of establishing and updating the benchmark and risk adjusting ACO expenditures, we agree with commenters' suggestions for taking a categorical approach to calculating ACO expenditures. Consistent with our policies stated elsewhere in section II.G. of this final rule, we are adopting a policy whereby performance year expenditures will be calculated for cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries, as described in section II.G.2.b. of this final rule.

Final Decision: We are finalizing our proposal under § 425.602, § 425.604, and § 425.606 to take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including individual beneficiary identifiable payments made under a demonstration, pilot, or time limited program, when computing average per capita Medicare expenditures under the ACO. Further, we will calculate ACO expenditures for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. Lastly, as specified in section II.C. of this final rule, we will use a 3-month run-out of claims data and a completion factor to calculate performance year expenditures.

(a) Impact of IME and DSH

In the proposed rule, we explained that teaching hospitals receive additional payment to support medical education through an IME adjustment. In addition, hospitals that serve a disproportionate share of low-income beneficiaries also receive additional payments, referred to as the Medicare DSH adjustment. Many hospitals, especially academic medical centers, receive both adjustments, which can provide substantial increases in their Medicare payments compared to hospitals that do not qualify for these adjustments. We stated our belief that the higher payments provided to these types of hospitals could provide ACOs with a strong incentive to realize savings simply by avoiding referrals to hospitals that receive IME and DSH payments.

In developing the proposed rule, we considered whether it would be appropriate to remove IME and DSH payments or a portion of these payments from the benchmark and the calculation of actual expenditures for an ACO. However, we explained that because of our limited statutory authority under section 1899(d) of the Act, we could adjust the benchmark under this provision by removing IME and DSH payments, but we could not also do so in our calculation of performance year

expenditures. We further noted reasons for including these payments in the calculation of both the benchmark and performance year expenditures. First, if we were to remove IME and DSH payments from the benchmark, the benchmark would be set artificially low relative to the performance period, thus making it more difficult for an ACO to achieve savings under this program. Second, excluding these payments could result in an artificial and incomplete representation of actual spending of Medicare Trust Fund dollars. Third, section 1899(d)(1)(B)(ii) of the Act requires that we update an ACO's benchmark during each year of the agreement period based on ''the projected absolute amount of growth in national per capita expenditures for parts A and B under the original Medicare fee-for-service program* * *.,'' which would necessarily include the effects of these payments. Lastly, including all relevant Medicare costs in an ACO's benchmark would maintain sufficient incentives for ACOs to ensure their assigned beneficiaries receive care in the most appropriate settings. We indicated, for example, that this could advantage ACOs which include teaching hospitals or DSH hospitals because their benchmarks would be set higher, and they could potentially earn shared savings when they refer patients to a more appropriate, less intensive care setting. We proposed not to remove IME and DSH payments from the per capita costs included in an ACO's benchmark. We invited comment on this proposal.

Comment: While a few comments supported our proposal not to remove IME and DSH payments from the benchmark, most comments urged us to use our authority under section 1899(i) of the Act to remove IME and DSH from both the benchmark and performance year expenditures. Others suggested that section 1899(d) of the Act provides implicit authority to adjust the performance year expenditures for ''other factors,'' such as IME and DSH payments. Many commenters favoring exclusion of IME and DSH payments also recommended that CMS exclude direct graduate medical education (DGME) payments.

Commenters explained that our proposed policy would incentivize ACOs to avoid referring beneficiaries to higher-cost academic medical centers, thus limiting beneficiary access to high quality, medically necessary care. One commenter pointed out that the inclusion of IME and DSH payments to teaching hospitals in establishing the benchmark may be attractive to ACOs because it would generate a higher benchmark against which an ACO could work to achieve savings. However, on the performance side, ACOs may see the cost structure of teaching hospitals as too prohibitive to achieve the desired savings during the performance years. Or, as another commenter suggested, ACOs may be motivated to shift their referrals away from academic centers so as to achieve apparent savings due to avoiding education-related payments, and not due to achieving actual efficiencies. Commenters expressed concern that the proposed policy could ultimately decrease support for the societal benefits provided by teaching hospitals, including the training of health professionals, discovery of advanced treatments, and ensuring the presence of the highest level of clinical care in a community. Several commenters also suggested that the proposed policy disadvantages hospitals serving low income populations, including those which serve a large number of Medicare and Medicaid patients.

Other comments supported inclusion of teaching hospitals in ACOs participating in the Shared Savings Program because of their potential to achieve the program's goals. One commenter noted that teaching hospitals tend to offer a wider variety of technologically sophisticated services, such as transplant services, compared to what is available at other hospitals, and, as a result, attract sicker patients, requiring more complex and costly treatments. This commenter further suggested that teaching hospitals are well positioned to generate savings and improve quality through better care coordination under the Shared Savings Program.

One commenter noted that certain State policies may lead to a discrepancy between Federal DSH payments to hospitals and the amount actually received by DSH hospitals. The commenter described a policy in the Texas under which a portion of a hospital's Federal DSH payment accrues to the State general revenue fund instead of the institution.

Several commenters suggested alternatives to excluding IME and DSH payments. One commenter recommended that CMS exclude teaching and DSH payments from the benchmark and savings calculations except for ACOs that include at least one major teaching hospital and one hospital that receives high DSH payments, or a single hospital that satisfies both criteria. This commenter further recommended that we account for other reforms under the Affordable Care Act that relate to hospitals that receive high DSH payments. Other commenters suggested that, in the longer term, CMS use risk adjustment methodologies or additional metrics to assess savings and quality improvements specific to hospitals receiving IME and DSH payments. In the event that CMS decides to favor including IME and DSH costs in the calculation of the benchmark and performance year expenditures, one commenter suggested that ACOs that include hospitals receiving IME and DSH adjustments should have an opportunity to receive additional shared savings payments, as we proposed for ACOs including FQHCs and RHCs as participants.

Response: We are modifying our proposal in order to adopt an alternate payment methodology that excludes IME and DSH payments from ACO benchmark and performance year expenditures, as authorized by section 1899(i) of the Act. We believe that care should be provided in the most appropriate setting whether it be a physician office, outpatient clinic, community hospital or teaching hospital. We further recognize the role of teaching hospitals in providing high quality, medically necessary care to Medicare beneficiaries. Commenters have persuaded us that including IME and DSH payments in determining ACO cost performance could create incentives for ACOs to avoid appropriate referrals to teaching hospitals in an effort to demonstrate savings. We remain committed to the societal benefits supported through IME and DSH payments, such as educating the nation's medical workforce, advancing the state of medical science, and ensuring access to care by vulnerable populations.

To exercise our authority under section 1899(i) of the Act, we must demonstrate 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.'' First, we believe that the intent of the program is to reward the prevention of unnecessary services and redundancies in care. By removing IME and DSH payments from benchmark and performance year expenditures we can reward more accurately actual decreases in unnecessary utilization of health care services. Second, excluding IME and DSH payments from determinations of ACO financial performance could help ensure participation of hospitals receiving IME and DSH payments in

ACOs, and their engagement in the accountable care model. We believe that removing the disincentive for ACOs to refer patients to teaching hospitals will help ensure beneficiaries continue to be referred to the most appropriate place of service for their care. In combination, these factors could result in Medicare beneficiaries receiving higher quality, better coordinated and more cost-efficient care in these settings. For these reasons, we do not expect that excluding IME and DSH payments from the determinations of ACO financial performance will result in greater payments to ACOs than would otherwise have been made if these payments were included. However, we intend to monitor this issue and will revisit it if we determine that excluding these payments has resulted in additional program expenditures.

Compared to other alternatives suggested by commenters, we believe that excluding IME and DSH payments from the determination of an ACO's eligibility for shared savings is presently the most effective approach to ensure participation by hospitals that receive IME and DSH payments. We plan to monitor this issue to help us determine whether these adjustments should be maintained and may revisit it in future rulemaking as we gain more experience with the Shared Savings Program.

DGME payments are made outside of the payments of Parts A and B claims. By virtue of this fact, under the methodology in either our proposed or final rules, DGME payments would not be included in an ACO's benchmark and performance year expenditures. Therefore, we do not need to make adjustments to individual claims for these payments.

Final Decision: We are modifying our proposal under § 425.602, § 425.604, and § 425.606 so as to exclude IME and DSH payments from ACO benchmark and performance year expenditures.

(b) Geographic and Other Payment Adjustments

In addition to IME and DSH payments, in the proposed rule we also considered whether to include or exclude a number of other payments from ACO benchmark and performance year expenditures.

In the proposed rule we explained that another factor in the Medicare FFS payment systems that could affect an ACO's ability to realize savings is the geographic payment adjustment applied under Medicare payment systems (for example, the IPPS wage index adjustments and the physician fee schedule geographic practice cost index (GPCI) adjustments). These adjustments increase and decrease payments under these systems to account for the different costs of providing care in different areas of the country. We further noted that there have been a number of temporary legislative adjustments to the wage indexes for various parts of the country during recent years. In some cases these have been extended on virtually an annual basis while others have been updated more intermittently. The timing of these adjustments could result in changes being made during an ACO's agreement period and between the benchmark and the performance years, thus influencing an ACO's ability to realize savings under the program.

We explained that, as in the case of IME and DSH adjustments, under section 1899(d)(1)(B)(i) and (ii) of the Act, we could adjust the benchmark by removing geographic payment adjustments, but we could not make a similar adjustment to performance year expenditures. Consistent with our proposed treatment of IME and DSH payments, we proposed not to remove geographic payment adjustments from the calculation of benchmark expenditures. We welcomed comment on this issue, and in particular the likely impact of this proposal in areas that are affected by temporary geographic adjustments.

Further, we addressed bonus payments and penalties for eligible professionals and hospitals. We proposed to exclude from ACO benchmark and performance year expenditures incentive payments for eligible professionals under section 1848 of the Act for the Physician Quality Reporting System, eRx, and EHR. We explained that section 1899(b)(3)(D) of the Act provides authority for the Secretary to incorporate these incentive payments into the Shared Savings Program, as the Secretary determines appropriate. The statute further provides that these incentive payments ''shall not be taken into consideration when calculating any payments otherwise made under subsection (d).'' We reasoned that section 1899(b)(3)(D) of the Act does not, however, provide authority for the Secretary to exclude Medicare expenditures or savings for incentive payments and penalties under other provisions of the Act from benchmark and actual expenditures. Therefore, we proposed to include in both the computation of actual expenditures and benchmark expenditures for Part A and B services any incentive payments not made under section 1848 of the Act that are reflected in Part A and B claims for services furnished to assigned FFS beneficiaries, such as EHR incentive payments to hospitals and payments under the Hospital Inpatient Value-Based Purchasing Program, which are made under section 1886 of the Act, and EHR incentive payments to CAHs, which are made under section 1814 of the Act.

We explained that incentive payments for programs such as these can affect actual expenditures and the benchmark, and thus an ACO's ability to realize savings. For example, an ACO's chances to share in savings or the level of savings that would be shared with the ACO would be reduced when an ACO professional or hospital participating in the ACO fails to receive an incentive payment (or is penalized with a payment reduction) under one of these programs during a benchmark year and subsequently receives an incentive payment from that program in an ACO performance year. This is because, all else being equal—(1) the ACO's expenditures in the performance year would be higher than they would have been in the absence of the incentive; and (2) the ACO's expenditures during the benchmark year would be relatively lower than they would have been had an incentive been received. Conversely, an ACO would be more likely to share in savings if it received an incentive payment under one of these other programs in a benchmark year and received no incentive or was penalized during a performance year. We stated our belief that the effect of including these incentive payments in the calculation of the benchmark and actual expenditures could create perverse incentives with the result that participation in the Shared Savings Program has the potential to adversely affect the performance of providers of services and suppliers with respect to other important Medicare efforts. We further stated that excluding these costs and savings would reduce the chances that incentives that were intended to encourage and reward participation in one Medicare program would discourage full participation in another.

Comment: MedPAC, among other commenters, suggested standardizing costs for ACOs, so that ACOs would be judged based on their success in controlling the growth in service use by their patients isolated from payments unrelated to resource use or changes in prices (such as input prices in their markets) that may be outside of ACOs' control. These commenters were among those that urged CMS to use its implicit authority under section 1899(d) of the Act or its authority under section 1899(i) of the Act to make additional adjustments to exclude certain claims-

based payments including: IME and DSH payments, geographic adjusters (such as payments based on the area wage index), GPCI, HVBP bonuses, hospital EHR incentive payments, transitional pass-through payments for new technologies, primary care incentive payments, and low cost county payments. Absent existing statutory authority to make these adjustments, some commenters suggested that CMS request that Congress amend the statute to allow for this possibility. The focus of other comments was on ensuring that any adjustments, or the lack thereof, to the benchmark be applied consistently to the calculation of performance year expenditures. One commenter cautioned that the data used for some cost-based incentive payments may be flawed.

Of the comments received, most favored excluding geographic payments from benchmark and performance year expenditures. In particular, commenters specified the exclusion of payments based on the following: area wage index, low cost county payment adjustments, GPCI, and the frontier States policy adjustment. Several commenters expressed concerns about including geographic payment adjustments in the benchmark calculations. One commenter, capturing the concerns indicated by several others, explained their view that variations in cost growth across geographic areas as well as inaccuracies in current CMS methods for accounting for differences in local input and practice costs (recently reviewed by the Institute of Medicine) may create incentives that reward ACO formation in some markets compared to others. For instance, some commenters were especially concerned that the GPCI, which differentially advantages providers based on location, is based on outdated payment location definitions. Another commenter suggested that inclusion of these geographic payment adjustments could have unintended consequences for referral patterns by ACOs, such as driving referrals based on geographic wage adjustments rather than performance. Others were generally concerned about including geographic payment adjustments that would disadvantage some ACOs more than others. Several commenters urged CMS to consider the findings from the Institute of Medicine's study on the impact of geographic adjustment factors on Medicare payment policy before addressing geographic payment adjustments in the Shared Savings Program.

Commenters agreed with the proposed exclusion of bonus payments for eligible professionals, in particular PQRS, eRx, and EHR incentives from benchmark and performance year expenditure calculations. Many commenters urged exclusion of all incentive bonus payments and penalties from calculations of the benchmark or the performance year expenditures.

Many commenters expressed concern that inclusion of Hospital EHR incentives and HVBP payments in ACO cost calculations could send mixed messages to hospitals, and could result in misaligned incentives. For example, several commenters suggested that by including VBP incentive payments in the cost of patient care, the proposed methodology for determining average per beneficiary costs would penalize ACOs with high quality hospitals. Similarly, as another commenter noted, ACOs could be penalized for including hospitals that earn EHR incentives during their agreement periods. Commenters described the consequences of including hospital EHR incentives and HVBP payments in calculating ACO financial performance, namely the proposed policy could force hospitals to choose between participating in the Shared Savings Program and other Medicare initiatives, which could result in discouraging hospital participation in ACOs. One commenter noted the importance of ensuring that incentives of the various programs are properly aligned so that their interactions support rather than impede each of the programs' goals. To this end, most commenters favored excluding EHR incentive payments to hospitals and CAHs as well as payments under the HVBP program from ACO benchmark and performance year expenditures. Further, one commenter suggested excluding EHR incentive payments for hospitals because the EHR bonus payments are not calculated on a per beneficiary basis and therefore will be difficult to apportion among assigned beneficiaries, and also because reductions in expenditures when the EHR incentives expire in future years will not be due to any change in the quality of patient care furnished by the hospitals.

Response: Some incentive payments and penalties discussed in the proposed rule are included in payments for Parts A and B services, for example, payments to hospitals through the Hospital Inpatient Value-Based Purchasing Program, which will be made under section 1886 of the Act. Other incentives we discussed, such as PQRS, eRx, and EHR incentives to eligible professionals, hospitals and CAHs are paid outside of payments for Parts A and B services. We wish to clarify that some bonus payments and penalties paid outside of Part A and B claims would be effectively excluded from the benchmark and performance year expenditures because of our proposal to take into account payments made from the Medicare Trust Fund for Parts A and B services furnished to assigned Medicare FFS beneficiaries when determining ACO's historical and actual costs. This is because bonus payments made outside of Parts A and B claims would not be captured in either the benchmark and performance year expenditures.

We are encouraged by the comments supporting our proposed methodology which would exclude payments that fall outside of Part A and B claims in calculating the benchmark and performance year expenditures; for example, DGME payments, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals.

We believe it is appropriate to finalize our proposal to include all Part A and B expenditures with the exception of the IME and DSH adjustments, as previously discussed, in the calculation of the benchmark and shared savings payments (that is, we would not standardize payments for example, by making adjustments for geographic or HVBP payments). We have experience with the PGP demonstration which calculated all Part A and B expenditures without such adjustments. Unlike the IME/DSH adjustments, we do not believe these other payments that are included in Part A and B expenditures (such as geographic payment adjustments, and HVBP payments) would result in a significant incentive to steer patients away from particular hospitals or providers since ACOs will be compared to their own historical expenditure benchmark as updated. Additionally, we are concerned about the complexity resulting from standardizing payments, given its relatively minor impact under our benchmarking methodology. However, we intend to evaluate this issue and may address it in future rule-making.

Final Decision: We are making final our proposal under § 425.602, § 425.604, and § 425.606 to include all Parts A and B expenditures, with the exception of IME and DSH adjustments, in the calculation of the benchmark and performance year expenditures. However, we intend to evaluate this issue and may address it in future rulemaking.

(3) Trending Forward Prior Year's Experience To Obtain an Initial Benchmark

Section 1899(d)(1)(B)(ii) of the Act requires the use of ''* * * the most recent available 3 years of per-beneficiary expenditures for parts A and B services * * *.'' to estimate a benchmark for each ACO. As the statute requires the use of historical expenditures, the per capita costs for each year must be trended forward to current year dollars and then averaged using the weights previously described to obtain the 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.

(a) Growth Rate as a Benchmark Trending Factor

The statute does not specify the trending factor to be used in estimating the initial benchmark. In the proposed rule we considered two options for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. We considered trending these expenditures forward using growth rates in expenditures for Parts A and B services for FFS beneficiaries. We also considered trending these expenditures forward using a flat dollar amount equivalent to the absolute amount of growth in per capita expenditures for Medicare Parts A and B under the FFS program.

We explained that a growth rate would more accurately reflect each ACO's historical experience. That is, in contrast to a flat dollar amount, a growth rate would neither raise the bar for ACOs in historically higher growth rate areas nor lower it for ACOs in lower growth areas. We also noted that use of a growth rate could perpetuate current regional differences in medical expenditures. We explained our belief that use of a flat dollar amount for a trending factor was more consistent with the method designated by the under section 1899(d)(1)(B)(ii) of the Act for updating the benchmark during the agreement period. Further, we indicated that use of a flat dollar trending factor could provide a stronger incentive for ACO development in areas with historically lower expenditures and growth rates. Conversely, potential ACOs in areas with historically higher growth rates could be reluctant to participate in the program because the challenge to reduce their growth rate would be greater in these areas relative to low expenditure, low growth ones.

We explained that, on balance, we believed that for purposes of establishing an initial expenditure benchmark, expenditures should be trended forward in a relatively neutral and comparable way across geographic areas. Therefore, we proposed to trend forward the most recent 3 years of per-beneficiary expenditures using growth rates in per beneficiary expenditures for Parts A and B services. We provided an example of how an ACO's historical experience would be trended forward. We would use 2009, 2010, and 2011 claims year data to set the benchmark for an ACO starting its agreement period January 1, 2012. The 2009 and 2010 data would be trended forward using the factor described later in this final rule so that all benchmark dollars would be in 2011 dollars. We welcomed comment on this proposal, and especially on whether use of a flat dollar amount to trend the benchmark would be more consistent with our proposal to update the benchmark as specified under section 1899(d)(1)(B)(ii) of the Act.

Comment: Commenters generally agreed with the proposed use of a growth rate, as opposed to a flat dollar amount, to trend forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. One commenter expressed concerns that a flat dollar trending factor would not account for either high cost geographic areas or annual growth in payments to hospitals (such as IME and DSH payments) outside the ACO's control, and that the flat dollar amount would be based on growth rates across all Medicare beneficiaries (those assigned to and not assigned to ACOs). Based on CMS' experience with the PGP demonstration and the benchmarking methodology for the PGP Transition demonstration, one commenter generally recommended that we use separate benchmarks for specific groups of beneficiaries—specifically the aged, disabled and ESRD populations—to account for significant variations in the costs of these beneficiaries. Another commenter suggested that we weight the concentration of Medicaid spending by categorizing patients into tiers based on their level of Medicaid spending.

Response: We are finalizing our proposal to use a growth rate as a trending factor. Further, we were persuaded by comments pointing to the need to account for variation in costs between different populations of Medicare beneficiaries. We believe that trending forward the benchmark expenditures, and updating the benchmark (as explained later in this final rule), for several categories of beneficiaries would provide a more accurate benchmark compared to the methodology we proposed. Expanding upon the commenter's suggestions, we are finalizing our proposal and clarifying that we will add to our methodology for trending the benchmark the calculation of separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries, as specified in section II.G.2.b. of this final rule. We believe that trending historical expenditures for these four categories provides a more complete and accurate benchmark for an ACO since it captures more accurately the proportion of ACO assigned patients that make up these categories, their expenditure growth patterns, and changes in the health status of these patients over time. It will also enable us to provide a more accurate risk adjustment as described in section II.G.2.c.1. of this final rule for an ACO's patient population, by capturing changes in the composition of the patient population over time, while reducing the impact of changes in the health status of an ACO's population due to more complete and accurate coding.

Final Decision: In establishing an ACO's benchmark, we are finalizing our proposal under § 425.602 to trend forward the most recent 3 years of per-beneficiary expenditures using growth rates in per beneficiary expenditures for Parts A and B services. That is, we will trend BY1 and BY2 forward, based on a growth rate, to BY3 dollars. Further, to trend forward the benchmark, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(b) National Growth Rate as a Benchmark Trending Factor

In the proposed rule, we considered use of national, State or local growth factors for trending the benchmark. We explained that using the national growth rate in Medicare A and B FFS expenditures appeared to be more consistent with the methodology that was specified in statute for updating each ACO's benchmark. Further, a national growth rate would allow a single growth factor to be applied to all

ACOs regardless of their size or geographic area. However, a national rate could also disproportionately encourage the development of ACOs in areas with historical growth rates below the national average that would benefit from having a relatively higher base, which increases the chances for shared saving, while discouraging the development of ACOs in areas with historically higher growth rates above the national average that would have a relatively lower base.

In contrast, we explained that trending expenditures based on State or local area growth rates in Medicare A and B expenditures may more accurately reflect the experience in an ACO's area and mitigate differential incentives for participation based on location. Therefore, we considered an option to trend the benchmark by the lower of the national projected growth rate or the State or the local growth rate. This option balanced providing a more accurate reflection of local experience with not rewarding historical growth higher than the national average. We believed this method would instill strong saving incentives for ACOs in both high-cost growth and low-cost growth areas.

We proposed to employ the national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. We believed this approach would help to ensure that ACOs in both high spending, high growth and low spending, low growth areas would have appropriate incentives to participate in the Shared Savings Program. We further indicated that this approach would allow us to move toward establishing a national standard to calculate and measure ACO financial performance. We sought comment on this proposal and on the alternatives to using a national growth rate.

Comment: Some commenters supported the proposal to employ a national growth rate, however many more favored use of either local, regional, or State growth rates. Commenters expressed concerns that the use of a national growth rate would discourage participation of ACOs in higher cost areas, including areas where many academic medical centers are located, where there is a high prevalence of chronic illness, or in States (such as Vermont) that have increased health care spending due to initiatives to expand health insurance coverage. These commenters suggested that benchmarking using more localized growth rates could reflect the experience of ACOs in different geographic settings, as well as local economies and local populations, and thereby encourage ACOs to participate nationwide, instead of only in certain pockets of the country. Others urged CMS to adopt policies which would not disadvantage already efficient providers or those operating in lower cost areas of the country.

Several commenters recognized the importance of using national growth rates, for rationalizing overall spending across regions nationwide, but thought it premature to introduce this approach to benchmarking at the outset of the program: suggesting instead that we begin with a local or regional growth rate and migrate to a national growth rate over time. One commenter favored the alternate option we considered, to trend the benchmark by the lower of the national projected growth rate or the State or the local growth rate, whereas several others suggested using the lower of either the national or local growth rates. In addition, commenters offered a number of alternative approaches for trending benchmark expenditures, including the following:

- Use a blend of national average growth and absolute dollar growth, such as that planned for the Pioneer Model ACOs.
- Use the ACO's own percentage growth rate to trend forward the historical benchmark data.
- Account for local variation after analyzing national and local growth rates.
- Account for adjustments for new technology costs.

Response: We believe that implementing a historical benchmark trending factor using the national growth rate for Parts A and B FFS expenditures appropriately balances commenters' concerns that benchmark trending should encourage participation among providers that are already efficient or operating in low cost regions without unduly rewarding ACOs in high-cost areas. The net effect of using the same trending factor for all ACOs will be to provide a relatively higher expenditure benchmark for low-growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. ACOs in high cost high growth areas have an incentive to reduce their rate of growth more to bring their costs more in line with the national average; while ACOs in low cost low growth areas have an incentive to continue to maintain or improve their overall lower spending levels. Therefore we are finalizing our proposal to use a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO.

As we proposed, using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, we will determine the national growth rates for the first and second benchmark years and trend expenditures for these benchmark years forward to the third benchmark year (BY3) dollars. Further, to trend forward the benchmark, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

Final Decision: We are finalizing our proposal under § 425.602 to use a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. In doing so, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

d. Updating the Benchmark During the Agreement Period

Section 1899(d)(1)(B)(ii) of the Act states that the benchmark shall be ''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.'' We considered two options for updating the benchmark during the agreement period, but proposed to use a flat dollar amount equivalent of the absolute amount of growth in the national FFS expenditures. We explained our view that in enacting section 1899(d)(1)(B)(ii) of the Act, Congress demonstrated interest in mitigating some of the regional differences in Medicare spending among ACOs and that this approach would help to ensure that ACOs in both high spending/high growth and low spending/low growth areas would have appropriate incentives to participate in the Shared Savings Program. We described the effect this update methodology might have in the second and third years of an agreement period: using a flat dollar increase, which would be the same for all ACOs, provides a relatively higher expenditure benchmark for low growth, low spending ACOs and a relatively lower benchmark for high growth, high

spending ACOs. All else being equal, an ACO can more likely share in savings when its actual expenditures are judged against a higher, rather than a lower benchmark. Thus, with a flat dollar increase to the benchmark, ACOs in high cost/high growth areas must reduce their rate of growth more to bring their costs more in line with the national average. We acknowledged that this approach to updating the benchmark could contribute to selective program participation by participants in low growth areas that could result in Medicare costs due to an increase in the amount of bonus payments for unearned savings.

We also considered and sought comment on a second option which would be to use our authority under section 1899(i) of the Act to update the benchmark by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/State projected absolute amount of growth in per capita expenditures. This option could instill strong saving incentives for ACOs in low-cost areas, as well as for those in high-cost areas. Incorporating more localized growth factors reflects the expenditure and growth patterns within the geographic area served by ACO participants, potentially providing a more accurate estimate of the updated benchmark based on the area from which the ACO derives its patient population. Capping the update at the projected absolute amount of growth in national per capita expenditures, however, can advantage ACOs in low cost/low growth areas that have already achieved greater efficiencies, while still offering a strong incentive for those in high cost/high growth areas to reduce their spending.

Comment: Commenters were mixed in their preference for either the proposed policy of updating benchmark by absolute growth in national FFS expenditures, or use of the lower of the national projected absolute amount or the local/State projected absolute amount. For example, one commenter disagreed with the option to use the lower of the national projected absolute amount or the local/State projected absolute amount, suggesting it negatively prejudges all high growth sectors without regard to the underlying clinical or quality issues. However, another commenter favored this approach because this adjustment would afford ACOs the greatest potential for achieving shared savings and minimize the threat of an ACO being disadvantaged by virtue of pricing within its geographic location. Along these lines, one commenter felt the proposed approach offered insufficient incentives for efficient providers to form an ACO. More generally, many commenters urged CMS to adopt policies to encourage participation by organizations that are already efficient or in low cost areas.

Several commenters urged use of regional or market-specific expense data for calculating the benchmark update. One commenter questioned whether the update would occur in the first performance year, as we specifically mentioned the potential effect resulting from the update in the second and third performance years.

Response: We considered commenters' suggested alternatives, but on the whole we believe our proposed method for updating the benchmark could best address the program's goals and commenters' overall concerns about the participation of efficient/low cost ACOs. The net effect of using the same update for all ACOs is to provide a relatively higher expenditure benchmark for low growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. Further, with a flat dollar increase to the benchmark equivalent of the absolute amount of growth in the national FFS expenditures, ACOs in high cost, high growth areas must reduce their rate of growth more (compared to ACOs in low cost, low growth areas) to bring their costs in line with the national average.

In light of the alternatives we considered, we disagree with the commenter who indicated that the proposed updating methodology offers insufficient incentives for efficient providers to form ACOs. Benchmarks for efficient/low cost providers updated to account for growth in regional or local expenditures would be comparatively lower, and therefore less advantageous, than benchmarks updated based on national experience. Thus, under the proposed update methodology, low cost ACOs could achieve a greater amount of savings, based on the same performance, than a comparable ACO in a higher cost area. Moreover, we believe that a benchmark methodology which encourages providers in higher cost areas to bring their spending more in line with the national average is a desirable outcome in furtherance of the program's goal of lowering Medicare expenditures. Lastly, updating the benchmark during the agreement period using a national growth factor aligns with our approach of using a national growth rate to trend forward base year expenditures to obtain the initial benchmark. This could facilitate analysis of trends in ACO financial performance relative to national trends in Medicare expenditures. For these reasons, we are finalizing our proposal to use the flat dollar amount equivalent of the projected absolute amount of growth in the national FFS expenditures to update the benchmark. Also, to clarify, the proposed update to the benchmark will occur in each year of the agreement period.

Comment: Based on CMS' experience with the PGP demonstration and the benchmarking methodology for the PGP Transition demonstration, one commenter generally recommended that we use separate benchmarks for specific groups of beneficiaries—specifically the aged, disabled and ESRD populations—to account for significant variations in the costs of these beneficiaries. Another commenter suggested that we weight the concentration of Medicaid spending by categorizing patients into tiers based on their level of Medicaid spending. Another commenter asked whether the projected absolute amount of growth in national per capita expenditures for Parts A and B would be scaled to reflect risk differences between the ACO and the Medicare average.

Response: To clarify, we will not risk adjust (that is, based on the CMS–HCC model) the flat dollar amount used to update the benchmark. However, as discussed in section II.G.2.c.(1). of this final rule, the updated benchmark will be adjusted relative to the risk profile of the performance year assigned beneficiaries. We agree with commenter's concerns about the need to account for variation in costs between different populations of Medicare beneficiaries. To align with our modified methodology for trending the benchmark, we will also make category-specific adjustments when updating the benchmark. We believe that updating the benchmark for several categories of beneficiaries would provide a more accurate benchmark compared to what we proposed, as applying national growth dollars to each of the benchmark strata separately reflects the different expected growth rates for these types of beneficiaries. Consistent with our policies stated elsewhere in section II.G. of this final rule, we are modifying our proposal to incorporate into the methodology for updating the benchmark the calculation of separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

Final Decision: We are finalizing our proposal under § 425.602 to update the benchmark 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 using data from CMS' Office of the Actuary. Further, in updating the benchmark, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

e. Determining Shared Savings

(1) Minimum Savings Rate

Section 1899(d)(1)(B)(i) of the Act states that ''an ACO shall be eligible to receive payment for shared savings * * * only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark * * *.'' We call this percent the minimum savings rate (MSR). Section 1899(d)(1)(B)(i) of the Act further specifies that the ''Secretary shall determine the appropriate percent * * * to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.'' Section 1899(d)(2) of the Act provides that, if an ACO has savings in excess of the MSR and meets the quality standards established by the Secretary, ''a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this title.'' We call the percent paid to the ACO the shared savings rate.

As we discussed in the proposed rule, a goal of the Shared Savings Program is to use a portion of the savings (the difference between the ACO's actual expenditures and the benchmark) to encourage and reward participating ACOs for coordinating the care for an assigned beneficiary population in a way that controls the growth in Medicare expenditures for that patient population while also meeting the established quality performance standards. However, observed savings can also occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. Thus, even if an ACO engages in no activities to improve the quality and efficiency of the services it delivers, in certain cases, differences between the benchmark expenditures (updated according to statute) and assigned patients' expenditures would be observed during some performance periods merely because of such normal variation. Consequently, under the one-sided model, the statute requires us to specify a MSR to account for the normal variations in expenditures, based upon the number of Medicare FFS beneficiaries assigned to the ACO. The MSR should be set in a way that gives us some assurance that the ACO's performance is a result of its interventions, not normal variation. However, we also do not want an outcome where savings that have been earned are not recognized.

Establishing an MSR on the basis of standard inferential statistics that take into account the size of an ACO's beneficiary population provides confidence that, once the savings achieved by the ACO exceed the MSR, the change in expenditures represents actual performance improvements by the ACO as opposed to normal variations.

Under the PGP demonstration, the MSR was initially set at a flat 2 percent of the benchmark, regardless of number of assigned beneficiaries, and PGP practices received back 80 percent of the savings achieved in excess of the MSR. However, in establishing a MSR, section 1899(d)(1)(B)(i) of the Act calls on us to take into account ''the number of Medicare fee-for-service beneficiaries assigned to an ACO.'' As such, we would need to apply statistical sampling techniques to determine a MSR based on the number of assigned beneficiaries with some level of statistical confidence.

The MSR in combination with the savings rate will determine the amount of shared savings that an ACO can receive. For example, fewer savings would be shared if the MSR were set at a higher percentage. Conversely, shared savings would be higher if the MSR were set at a lower percentage. There are several policy implications associated with the methodology used to set the MSR. A higher MSR would provide greater confidence that the shared savings amounts reflect real quality and efficiency gains, and offer greater protection to the Medicare Trust Funds. However, due to the larger barrier to achieving savings, a higher MSR could also discourage potentially successful ACOs, especially physician-organized ACOs and smaller ACOs in rural areas, from participating in the program. In contrast, a lower MSR would encourage more potential ACOs to participate in the program, but would also provide less confidence that savings are a result of improvements in quality and efficiency made by an ACO. In the proposed rule, we stated that we believed that the most appropriate policy concerning determination of the ''appropriate percent'' for the MSR would achieve a balance between the advantages of making incentives and rewards available to successful ACOs and prudent stewardship of the Medicare Trust Funds.

(a) One-Sided Model

For the one-sided model we proposed a sliding scale confidence interval (CI) based on the number of assigned beneficiaries. The MSR would be established for each ACO based on increasing nominal confidence intervals for larger ACOs so that an ACO with the minimum 5,000 assigned beneficiaries would have an MSR based on a 90 percent CI; an ACO with 20,000 assigned beneficiaries would have a MSR based on a 95 percent CI and an ACO with 50,000 assigned beneficiaries would have an MSR based on a 99 percent CI. In addition, the MSR would not be allowed to fall below 2 percent for larger ACOs. Table 6 displays the minimum savings rate an ACO would have to achieve before savings could be shared based on the number of its assigned beneficiaries. We proposed that an ACO that exceeds its MSR would be eligible to share up to 50 percent of the savings in the one-sided model (based on quality performance), as discussed in section II.F. of this final rule.

In order to improve the opportunity for groups of solo and small practices to participate in the Shared Savings Program, we proposed to vary confidence intervals by the size of the ACO, which is determined based on the number of assigned beneficiaries. In response to our November 17, 2010 RFI, many RFI commenters recognized the prevalence of solo and small practices and the importance of these providers for rural areas and for the treatment of specific patient populations, for example, individuals with mental health and substance abuse disorders or beneficiaries residing in skill nursing facilities. Many of these RFI commenters urged us to consider policies and models that encourage the participation of solo and small practices and to address barriers they face in forming ACOs, such as access to up-front capital to invest in the infrastructure and resources required to redesign care. One option that would help accomplish this would be to vary the confidence intervals used to establish MSRs so that smaller practices would have relatively lower MSRs. Conversely, in recognition that they are

likely to be already established, possess prior experience, and thus better able to achieve savings, larger ACOs would have their MSRs based on a higher confidence interval, resulting in a relatively higher MSR.

We proposed that the MSRs would be estimated to provide confidence that an ACO with a given number of beneficiaries and assumed to be of average national baseline per-capita expenditure and expenditure growth rate would be unlikely to achieve a shared savings payment by random chance alone. A specific MSR is a function of both the number of assigned beneficiaries and a chosen confidence interval. Recognizing the higher uncertainty regarding expenditures for smaller ACOs and the desire to encourage participation by smaller ACOs, for the one-sided model, we proposed to set the confidence interval at 90 percent for ACOs of 5,000 beneficiaries, resulting in an MSR of 3.9 percent. For ACOs with 20,000 and 50,000 beneficiaries, we proposed to set the confidence interval at 95 percent and 99 percent, respectively, resulting in MSRs of 2.5 percent and 2.2 percent. As ACO size increases from 5,000 to 20,000 (or similarly from 20,000 to 50,000), we proposed blending the MSRs between the two neighboring confidence intervals, resulting in the MSRs as shown later in the document in Table 6. We specified an MSR at both the high and low end of each range of ACO population size. A particular ACO would be assigned a linearly-interpolated MSR given its exact number of beneficiaries. For example, an ACO with 7,500 beneficiaries would be assigned an MSR of 3.3 percent because it lies at the midpoint between 7,000 and 7,999 beneficiaries, sizes at which the MSR would be 3.4 percent and 3.2 percent, respectively. For ACOs serving more than 60,000 assigned beneficiaries, we proposed that the MSR would not be allowed to fall below 2 percent. This lower bound was designed to protect the shared savings formula from expenditure reduction due to random chance that can occur in group claims due to factors that persist regardless of a group's size. This lower bound is also consistent with the flat 2 percent MSR we proposed to use in the two-sided model and is the minimum level that was used in the PGP Demonstration.

The proposed confidence intervals were determined assuming that the variation in the per capita expenditure growth for a particular ACO would be equal to the variation in per capita expenditure growth nationally. We acknowledged that this would not be the case for the majority of ACOs, however, as regional growth rates tend to vary from the national average due to a number of variables. Therefore, the confidence intervals generated using only the national expenditure growth variation would overstate the relative confidence associated with an increasing group size. This would be compensated for in two ways: (1) the 2 percent floor; and (2) increasing the confidence interval as group size increases.

TABLE 6—PROPOSED MINIMUM SAVINGS RATE BY NUMBER OF ASSIGNED BENEFICIARIES

[One-sided model]

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
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	

In the proposed rule, we stated that we would welcome comment on the most appropriate means to establish the MSR for an ACO, including the appropriate confidence intervals.

Comment: Several comments supported the proposed MSRs under the one-sided model. In particular, MedPAC specified that CMS should keep the proposed MSRs if it allows for a shared savings only track in the first agreement period. Most comments on this topic, however, expressed concern that the proposed methodology for establishing the MSR on a sliding scale based on population size would disadvantage smaller ACOs and discourage participation, particularly by setting a bar that is too high to encourage participation by smaller ACOs, including ACOs likely to form in rural areas and those largely comprised of small- and medium-sized physician practices. Some commenters considered the potential long term consequences of this dynamic, indicating it could ultimately result in diminished provider competition in some markets or stifle the development of innovative care coordination strategies.

Some commenters suggested it would be unfair to hold smaller ACOs to what they perceived to be a relatively higher MSR than what exists for larger ACOs. One commenter indicated that the MSR is financially beneficial to CMS at the expense of ACOs. Further, as other commenters indicated, smaller ACOs are likely to be in greatest need of additional capital to support start-up and operational expenses. One commenter suggested our proposal could make it harder for ACOs to continue to achieve savings in excess of the MSR as they become increasingly efficient over time. Some commenters suggested the MSRs may make it impossible for smaller ACOs to ever share in savings, particularly given the program's rigorous quality standards.

Thus, commenters recommended a variety of alternatives to the proposed MSRs. Most commonly, commenters suggested that we either— (1) apply a common threshold rather than a sliding scale, such as a flat 1 or 2 percent MSR, for all ACOs; or (2) reduce the MSR that

smaller ACOs must achieve. Several comments suggested that CMS generally adjust the sliding scale to be based on lower thresholds (for example, a range of 2 to 3 percent), eliminate the MSR, or eliminate it for certain ACOs. In lieu of an MSR, commenters offered alternate suggestions to protect against random variation such as making the percent of shared savings for which a provider is eligible inversely proportional to their percentile in expenditures per Medicare beneficiary. A number of commenters offered that other aspects of the proposed program, for example, the rigorous quality performance standards or the requirement that all ACOs ultimately accept downside performance risk, are sufficient to ensure savings are a result of actions by ACOs and obviate the need for an MSR. One commenter suggested a blended approach such that if an ACO exceeds the 2 percent MSR, it would be eligible for a lower sharing rate, but would not receive the full sharing rate unless it exceeded its statistically adjusted MSR. Another commenter suggested a rolling confidence interval option for small ACOs that would allow them to cumulate cost experience (and savings) over time. Under this approach, CMS would base the ACO's MSR on the sum of its assigned beneficiaries across all 3 years of participation (for example, a 5,000 member ACO would have the CI of a 15,000 member ACO over 3 years). Further, the commenter recommended allowing ACOs to include their entire patient base, including privately insured patients for purposes of computing their MSR. Another commenter asked whether CMS would consider rewarding those ACOs who can maintain lower costs than their initial MSR for 3 years. Finally, one commenter asked that we defend our assumption that variation within an ACO is comparable to national variation.

Response: We agree with comments by MedPAC and others supporting the proposed sliding scale, based on the size of the ACO's assigned population, to establish the MSR for ACOs under the one-sided model. In particular, given our decision to allow for a shared savings only model, we are following MedPAC's advice to retain the proposed MSR methodology. Alternatives suggested by commenters that allow for lower MSRs for smaller ACOs under the one-sided model (such as a flat 1 or 2 percent MSR for all ACOs) provide insufficient protection to the Medicare Trust Funds against shared savings resulting from random variation, absent some additional protection such as accountability for shared losses. We believe the relatively lower MSR under the two-sided model is appropriate since there is a balancing of the risk of random variation because the ACO is accountable for losses. Thus, while there is some minimal risk that an ACO will achieve savings due to random variation, there is also some risk that the ACO will incur losses due to random variation. Therefore, we find it appropriate to finalize the proposal to establish MSRs for ACOs under the one-sided model to protect the Trust Fund from paying out incentives for random variations in costs rather than for real improvements made by ACOs. With respect to the comments that expressed concern that our proposed MSR methodology did not provide appropriate incentives for smaller ACOs, we believe the change to our proposed methodology to provide for a shared savings-only track, in addition to other changes to increase the financial attractiveness of the program, will be sufficient to encourage participation.

The proposed MSRs were defined to recognize variation due to the number of beneficiaries assigned to the ACO, as required by the statute. Therefore in developing the proposed MSRs, we examined variation in expenditure growth rates for groups sampled on a national basis in order to isolate variation based on group size rather than regional factors that can cause added variation relative to the national average growth rate.

Final Decision: We are finalizing our proposal under § 425.604 to use a sliding scale, based on the size of the ACO's assigned population, to establish the MSR for ACOs participating under the one-sided model.

(b) Two-Sided Model

In the proposed rule, we stated that the MSR remains important under the two-sided model to guard against normal variation in costs, so that ACOs share savings or losses with the program only under those circumstances in which we can be confident that such savings or losses are the result of the ACO's behavior rather than normal variation. At the same time, we noted that we believed it was more appropriate to employ a fixed minimum savings rate under this model than under the one-sided model. First, given the potential for shared loss, the greater predictability of a fixed MSR is more likely to attract organizations to participate under this model. Second, greater protection to the Medicare Trust Fund is afforded by ACOs accepting the risk of paying Medicare back for losses. Therefore, based on our experience with the PGP demonstration and consistent with the lowest applicable MSR under the one-sided model, we proposed to adopt a fixed 2 percent MSR for organizations operating under the two-sided model, in place of the variable minimum savings rate for organizations operating under the one-sided model.

Comment: Commenters' suggestions for revising the proposed policy for the MSR for ACOs under the two-sided model largely tracked those described previously for the one-sided model. For instance, several commenters recommended removing the MSR from the two-sided model given ACOs' accountability for shared savings and losses under this model.

Response: We are finalizing our proposal to adopt a fixed 2 percent MSR for ACOs under the two-sided model. We find support for the application of a flat 2 percent MSR to ACOs participating in the two-sided model in commenters' suggestions that we apply a common threshold of 1 or 2 percent to all ACOs. We disagree with suggestions that we reduce, or eliminate altogether, the MSR in the two-sided model. Although greater protection to the Medicare Trust Fund is afforded by ACOs accepting the risk of paying Medicare back for losses, there remains a need to protect the Trust Fund from paying out incentives for random variations in costs rather than for real improvements made by ACOs. We continue to believe that a flat 2 percent MSR is appropriate for the two-sided model. As explained previously, unlike the one-sided model, under the two-sided model there is a balancing of risk of random variation because the ACO is accountable for losses. Thus, while there is some minimal risk that an ACO will achieve savings due to random variation, there is also some risk that the ACO will incur losses due to random variation. Further, as indicated in the proposed rule, a 2 percent MSR reflects the lowest MSR under the one-sided model and is also the MSR that was used in the PGP demonstration.

Final Decision: We are finalizing our proposal under § 425.606 to apply a flat 2 percent MSR to all ACOs participating under the two-sided model.

(2) Quality Performance Sharing Rate

As discussed in section II.F. of the proposed rule (76 FR 19620 and 19621), we proposed that ACOs choosing to participate in the one-sided model could share in savings if they exceed a MSR. For those ACOs whose savings exceed the MSR in the one-sided model, we proposed a savings sharing rate of up to 50 percent of total savings, above a 2 percent savings threshold, with a payment cap of 7.5 percent of an ACO's

benchmark. We also proposed an additional increase of up to 2.5 percentage points for including FQHCs and/or RHCs as ACO participants, as discussed in section II.F of the proposed rule. Thus, under our proposal, an ACO participating in the one-sided model could realize a maximum shared savings rate of 52.5 percent. Under the two-sided model, we proposed that an ACO that realized savings against its benchmark could qualify for a final sharing rate of up to 65 percent if it was eligible for the maximum adjustments. The 65 percent final sharing rate was comprised of a savings rate of up to 60 percent for quality performance, plus 5 percentage points for including FQHCs and/or RHCs as ACO participants.

Comment: Commenters favored allowing higher sharing rates based on ACO quality performance for both the one-sided and two-sided models, and offered a variety of rationales for increasing the sharing rate. Typically, commenters suggested that higher sharing rates would better incent participation, particularly considering the costs of ACO formation. Others indicated that the proposed shared savings percentages were too low when compared with other Medicare shared savings initiatives, such as the 80 percent shared savings rate under the Physician Group Practice Demonstration, and the higher sharing rates proposed by the Innovation Center for Pioneer Model ACOs.

Commenters suggested sharing rates ranging from 50 to 95 percent (most commonly 75 percent) under the one-sided model and 66 to 95 percent (most commonly 80 percent) under the two-sided model. MedPAC recommended increasing the sharing rates for both models, suggesting, for example, offering a savings rate of up to 75 percent for the one-sided model and 95 percent for the two-sided model for the first agreement period. Several commenters suggested we initially establish higher sharing rates than what was proposed, while incrementally decreasing the maximum sharing rate over time; for instance, setting the sharing rate at 75 percent or 95 percent for the initial performance year and then gradually tapering it off in subsequent years. Several commenters suggested approaches whereby ACOs meeting a quality standard would obtain a guaranteed minimum amount of shared savings, and thereafter receive an additional percentage of shared savings on a sliding scale based on higher quality performance. For instance, creating a minimum sharing rate of 50 percent for Track 1 and 60 percent for Track 2, and using an ACO's quality score to award additional shared savings up to a maximum sharing rate of 80 percent for Track 1 and 90 percent for Track 2.

One commenter suggested the sharing rates should be the same for both models. More commonly, however, commenters supported a policy of establishing different sharing rates for the two models, to provide a greater reward to ACOs taking risk. Some commenters recommended that CMS increase the difference in sharing rates between the models. Several commenters suggested maintaining or lowering the proposed sharing rate for the one-sided model, while increasing the sharing rate for the two-sided model. One commenter suggested downwardly adjusting the sharing rate for the one-sided model over time to encourage ACOs to move to the two-sided model. Others suggested higher sharing rates for certain types of ACOs, such as early adopters of the ACO model, or ACOs in low cost areas. Overall, commenters' suggestions for the amount of difference in the sharing rates between the two models ranged from zero to 40 percent, however most commenters tended to recommend differential of between 5 and 25 percent.

Response: We carefully considered commenters' requests for a higher sharing rate based on quality performance for both the one-sided and two-sided model as a means of encouraging participation in the program.

In the proposed rule we explained that the sharing rate based on quality performance was a function of equally weighting the five proposed domains for quality measurement. As such, under the one-sided model, each domain would account for 10 percent, for a total sharing rate of 50 percent. We further specified the need to differentiate between the program's models—to incent ACOs to take risk by offering the possibility of a greater financial reward—and proposed the two-sided model would have a maximum sharing rate based on quality performance of 60 percent, equally apportioned among the five measurement domains.

As specified in section II.F. of this final rule, in the final rule we have reduced the number of quality measures, and consequently are finalizing a quality performance standard which includes 4 domains that will be equally weighted for purposes of quality scoring. As discussed elsewhere in this section of this final rule, we are modifying our proposals to provide greater opportunity for ACOs to achieve shared savings, for instance, by allowing first dollar sharing under the one-sided model and raising the payment performance limits for both models.

We considered how to address the opposing views presented in the comments on the sharing rate for the one-sided model, including recommendations that providing a higher sharing rate would encourage participation in the program, and recommendations that we maintain or lower the sharing rate to ensure a sufficient incentive for ACOs to participate in the two-sided model. Given our modifications to the quality performance standard and financial models which will make it easier for ACOs to share in a savings, we believe that maintaining the proposed sharing rate for the one-sided model offers a fair balance between commenters' suggestions that we provide greater opportunities for ACOs to share in savings while also remaining protective of the Trust Funds.

We appreciate commenters' support of the need to differentiate financially between the two models by offering a higher sharing rate to ACOs under the two-sided model. We continue to believe that risk-based arrangements are more effective in driving behavior changes by providers, and therefore we should ensure there are appropriate incentives for ACOs to enter the program's two-sided model. We agree with commenters' recommendations that support our proposal to offer ACOs under the two-sided model a higher sharing rate than those under the one-sided model, as a means of encouraging ACOs to accept downside risk. Further, our proposal to differentiate the sharing rates for the models by 10 percent aligns with commenters' preference for a difference in sharing rates in the range of 5 to 25 percent. When compared to the 50 percent sharing rate based on quality for the one-sided model, we believe that a 60 percent sharing rate for the two-sided model offers an appropriate additional incentive for ACOs to accept downside risk.

Final Decision: We are finalizing our proposal under § 425.604 and § 425.606 that ACOs under the one-sided model can earn up to 50 percent of total savings based on quality performance and ACOs under the two-sided model can earn up to 60 percent of total savings based on quality performance.

(3) Additional Shared Savings Payments

In the proposed rule, we recognized the important role that FQHCs and RHCs play as safety net providers and in improving access to primary care for Medicare and Medicaid beneficiaries. Under the proposed rule, FQHCs and RHCs were unable to participate

independently in this program by forming their own ACOs. As a result, we believed that providing incentives to ACOs that include FQHCs and/or RHCs as ACO participants was in the interest of the Shared Savings Program as including these types of entities could promote care coordination and the delivery of efficient, high-quality health care. We proposed that ACOs could be eligible to receive higher sharing rates, based on a sliding scale, for including FQHCs and RHCs as ACO participants. Under the one-sided model we proposed up to a 2.5 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. Under the two-sided model we proposed up to a 5.0 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. We proposed establishing a sliding scale payment, outlined in the Table 7, based on the number of Medicare FFS beneficiaries with one or more visit at an ACO participant FQHC or RHC during the performance year.

TABLE 7—SLIDING SCALE PAYMENT BASED ON NUMBER OF BENEFICIARY VISITS AT AN ACO PARTICIPANT FQHC OR RHC

Percentage of ACO assigned beneficiaries with 1 or more visits to an ACO participant FQHC/RHC during the performance year	Percentage point increase in shared savings rate (one-sided model)	Percentage point increase in shared savings rate (two-sided model)
1–10 percent	0.5	1.0
11–20 percent	1	2.0
21–30 percent	1.5	3.0
31–40 percent	2	4.0
41–50 percent	2.5	5.0

We also proposed that ACOs specifically identify their FQHC/RHC participant TINs in their initial and annual reporting of ACO participant TINs, and disclose other provider identifiers as requested to assure proper identification of these organizations for the purpose of awarding the payment preference. Further, we proposed to define FQHCs and RHCs, for the purpose of awarding this payment preference, as these terms are defined in 42 CFR 405.2401(b) of our regulations. We sought comment on alternate options for establishing a payment preference with a sliding scale for ACOs that include FQHCs or RHCs as ACO participants, including suggestions for the appropriate method to measure FQHC/RHC involvement and the appropriate level of incentives.

Comment: While many commenters supported the concept of the proposed incentive, others found the incentive inadequate to encourage meaningful FQHC and RHC participation in ACOs. One commenter envisioned that FQHCs and RHCs would be ''latched on'' to the ACO in an attempt to achieve a greater share of savings. Commenters were also critical of the incentive's focus on care provided to ACO beneficiaries at FQHCs and RHCs when we proposed to assign beneficiaries to ACOs based on their use of other primary care providers. As one commenter explained, the incentive assumes an unlikely scenario where non-FQHC providers will refer a patient to an FQHC for care. Others considered the incentive, based on a one visit rule, ripe for gaming: ACOs might schedule their beneficiaries to have one visit at an FQHC or RHC to obtain the incentive, which could result in ''primary care discontinuities.'' One commenter questioned whether the incentive was in line with the letter and spirit of the Affordable Care Act.

Commenters provided various suggestions for how to revise the structure of the incentive, such as the following:

- Increasing the amount of the incentive, for instance to a 10 percent bonus under both models.
- Including Method I CAHs in the incentive payment structure.
- Providing additional payments for including multiple FQHCs.

Commenters also offered alternatives. For instance, one commenter recommended that CMS create incentives for FQHCs and RHCs to participate in ACOs, rather than to reward ACOs for including these organizations.

Response: In this final rule, we are eliminating our proposal to provide an incentive for ACOs to include FQHCs and/or RHCs as participants. We proposed this incentive to address our inability to determine a statutorily satisfactory way of assigning beneficiaries to an ACO on the basis of services furnished by these entities. However, given that we have determined an appropriate methodology for assigning beneficiaries to ACOs on the basis of services furnished by FQHCs and RHCs, therefore allowing FQHCs and RHCs to more fully participate in the program, we believe the incentive is unnecessary and has the potential to cause unintended consequences as articulated by commenters.

Final Decision: The final rule will not contain a sliding scale-based increase in the shared savings rate, up to 2.5 additional percentage points under the one-sided model and up to 5 additional percentage points under the two-sided model, for ACOs that include an FQHC or RHC as an ACO participant.

In the proposed rule we also discussed our interest in encouraging providers who serve a large portion of dual eligible beneficiaries to participate in the Medicare Shared Savings Program. We explained that Medicare beneficiaries who are also eligible for Medicaid—that is, are ''dually eligible'' for these programs—are among the most vulnerable of Medicare beneficiaries. Dual eligible beneficiaries tend to have higher medical costs than other FFS beneficiaries, and, as a result, are expected to benefit even more than other beneficiaries from improvements in the quality and efficiency of their care resulting from the greater care coordination offered by an ACO.

We also stated in the proposed rule that section 1899(j) of the Act provides that ''[t]he Secretary may give preference to ACOs who are participating in similar arrangements with other payers.'' The statute prescribes neither the kind of preference that the Secretary should provide to such ACOs nor what other types of arrangements should be considered ''similar'' for purposes of such a preference. We stated our belief that the more patients an ACO sees for which it is eligible to receive performance-based incentives, such as shared savings, the more likely it is that the ACO will adopt

substantial behavior changes conducive to improved quality and cost savings.

We sought comment on methods to provide preference to ACOs that serve a large dual-eligible population or that enter into and maintain similar arrangements with other payers. Specifically, we sought suggestions to encourage accountability for dual-eligible beneficiaries and participation in similar arrangements with other types of payers.

Comment: Comments described the health needs of dual eligible beneficiaries and the potential challenges of managing this population. Some commenters saw the need for CMS to ensure participation by providers that care for dual eligible beneficiaries as part of the larger issue of the need for CMS to support safety net providers and ACOs more generally. Many commenters favored policies that financially reward ACOs whose assigned populations include a larger proportion of dual eligible beneficiaries. Commenters offered a variety of suggestions on how to structure this payment preference, including the following:

- Higher shared savings rates for ACOs that serve a high percentage of dual eligible beneficiaries, similar to the increased sharing rate proposed for ACOs which included FQHCs and RHCs. Commenters' suggestions for higher sharing rates typically ranged from 2.5 percentage points to 20 percent under the one-sided model and 5 percentage points to 25 percent under the two-sided model.
- Additional incentives coupled with alternative payment models for an ACO whose patient mix is comprised mostly of Medicaid patients, and which care for large percentages for dual eligible beneficiaries.
- Exempt ACOs that treat a larger proportion of dual eligible beneficiaries from the 2 percent net sharing rate.
- Revised benchmarking methodology (for example, a ''separate savings target'') for ACOs that serve a large population of dual eligible beneficiaries.

Several commenters raised concerns about creating incentives for ACOs to care for dual eligible beneficiaries. One commenter noted that the proposed assignment methodology, under which FQHCs would not be the basis for assignment, would exclude many dual eligible beneficiaries from ACOs. By virtue of this policy, the commenter perceived proposed monitoring for avoidance of at-risk beneficiaries and the proposed rule's emphasis on providing incentives for ACOs to include dual eligible beneficiaries to be flawed. Another commenter, pointing to the unique health care needs of dual eligible beneficiaries, cautioned that ACOs should have the capacity and ability to serve these individuals; suggesting that CMS condition any dual eligible incentive payment on an ACO not only serving a large proportion of dual eligible beneficiaries, but also having the appropriate infrastructure to coordinate care and benefits for this population. One commenter opposed the use of financial incentives to encourage ACOs to serve dual eligible beneficiaries or to encourage providers serving duals to become ACOs, based on the belief that such financial incentives in the early days of the program may distort provider behavior in ways that are detrimental to beneficiaries and costly to the program. To effectively serve this population, this commenter indicated, for example, that we should ensure that ACO providers are Medicaid participating providers, and that an ACO serving many dual eligible beneficiaries has a relationship with the State Medicaid agency in the State in which it operates. This commenter further pointed out an effort by the Innovation Center in Connecticut to develop an Integrated Care Organization to serve dual eligibles in the State.

We received few comments on our statutory authority to give preference to ACOs who are participating in similar arrangements with other payers. One commenter recommended that CMS give preference to ACOs that have contracts with private payers that include financial accountability and quality performance incentives, and avoid requirements that could have a chilling effect on the willingness of private payers to invest in and partner with ACOs. This commenter further recommended that the definition of ''similar arrangement'' be consistent across the Shared Savings Program and the Pioneer ACO Model. On a related issue, many commenters expressed their support, generally, for the Innovation Center's Pioneer ACO Model. As a condition of participation in the Pioneer Model, ACOs must commit to entering outcomes-based contracts with other purchasers (private health plans, State Medicaid agencies, and/or self-insured employers) such that the majority of the ACO's total revenues (including from Medicare) will be derived from such arrangements, by the end of the second performance period in December 2013. One commenter requested clarification on the extent to which private payers could participate in ACOs.

In addition to the payment incentives and preferences discussed in the proposed rule, commenters recommended that CMS include a variety of other incentives based on an ACO's other quality improvement activities, and the composition of the ACO's participants or the particular populations they serve. For example, commenters suggested we include the following:

- Incentives for early adopters of the accountable care model.
- Incentives for caring for particular populations, such as rewarding ACOs that serve the uninsured, care for beneficiaries in rural areas, or that have diverse patient populations.
- Incentives for including the following providers and suppliers:
  - ++ Patient centered medical homes.
  - ++ Teaching hospitals.
  - ++ Ambulatory Surgery Centers.
  - ++ Community health organizations including Community Mental Health Centers.
  - ++ Home health and hospice agencies.
  - ++ Physicians practicing in rural areas.
- Incentives for including health programs operated by the Indian Health Service, tribes or tribal organizations, and urban Indian organizations.
- Incentives to encourage participation by small, rural, and physician-led ACOs.
- Incentives to ensure some primary care services are delivered by NPs and PAs.
- Incentives to move patients from the acute care setting to appropriate post-acute or outpatient providers.
- Incentives to reward participation in other quality improvement initiatives, such as physician-led quality improvement programs.
- Incentives to use telehealth and remote patient monitoring technologies in innovative modalities extending beyond what is currently reimbursed under FFS Medicare.
- Incentives for the development of primary care training in new models of care.
- Incentives for ACOs participating in clinical trials, to encourage innovation in health care.

Response: We are finalizing our proposal, which does not give preference to ACOs engaged in similar arrangements with other payers, or provide additional incentives for ACOs which care for dual eligible beneficiaries. Similarly, we do not intend to recognize other factors, such as the ACO's other quality improvement activities, the composition of the ACO's participants or the particular populations they serve. CMS' goal is to promote complete integration of care

and align incentives whether care is provided under Medicare, Medicaid, or both. ACOs are one valuable new option to assure greater coordination of care for Medicare Parts A and B services for dual eligible beneficiaries. Additionally, there are existing demonstrations and emerging care models underway in the Innovation Center in partnership with the Medicare-Medicaid Coordination Office which will provide further opportunities for the integration of care and financing across both Medicare and Medicaid, including long term services and supports. For dually eligible individuals CMS intends to study the effect of assignment of these individuals to ACOs in the Shared Savings Program on Medicaid expenditures, and may use this information in the development of future models for testing by the Innovation Center. We believe that these demonstrations and models targeting the dual eligible population will further address and create incentives for providers to focus on serving their special needs.

Through the flexibility allowed in the governance requirements, discussed in the Section II.B. of this final rule, we have left room for ACOs to engage with private payers. In addition, we may revisit our authority to award a preference to ACOs that participate in similar arrangements with other payers as we gain more experience with such arrangements through the Pioneer ACO Model.

We decline to incorporate incentives into this national program to account for the variety of approaches that ACOs may choose for their quality improvement activities outside the Shared Savings Program, as well as their provider and supplier composition and patient mix. We believe that the flexibility allowed in the distribution of shared savings provides the opportunity for ACOs to reward ACO participants' for engaging in other quality improvement initiatives.

We may revisit the issue of incentives related to ACO activities, composition, and patient mix as we gain experience with the ACO model through the Shared Savings Program and the Pioneer ACO Model.

Final Decision: The final rule will not contain additional financial incentives, beyond those established for quality performance, for the care of dual eligible beneficiaries or other factors related to the composition of the ACO or its activities, nor will the final rule include a preference for ACOs participating in similar arrangements with other payers.

(4) Net Sharing Rate

Section 1899(d)(2) of the Act calls for us to share ''a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO.'' Section 1899(i) of the Act permits the Secretary to consider other payment models if she determines that they will ''improve the quality and efficiency of items and services furnished under this title'' and will not result in additional expenditures. Thus, in considering the amount of savings ACOs under the one-sided model and two-sided model would be eligible to receive, we considered several options in addition to the methodology outlined in section 1899(d)(2)of the Act.

The first option we considered is the one required under section 1899(d)(2) of the Act, which would permit the ACO to share on first dollar savings once it achieves savings in excess of the MSR. This option would maximize the reward that an ACO could realize. This amount could provide critical financial support for ACOs that serve a smaller population (for example, less than 10,000 assigned beneficiaries), which may be physician only and/or predominantly care for underserved populations, or ACOs whose beneficiaries rely upon safety net providers for care or ACOs which serve rural areas. However, given the normal variation in expenditures, we had concerns that sharing on first dollar savings with ACOs under the one-sided model could result in sharing on unearned savings rather than on savings achieved by the ACO for redesigned care processes. We also explained that this concern was mitigated under the two-sided model, where ACOs are assuming the risk of losses due to normal year-to-year- variations in Medicare beneficiaries' claims expenditures.

We considered another alternative which would limit the amount of savings by requiring ACOs to exceed the MSR and then share with the ACO only those savings in excess of the MSR. As discussed previously, one challenge to appropriate sharing of savings under this program is that observed savings can occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. This concern is heightened in the one-sided model, because absent initial accountability for losses, ACOs have less motivation to eliminate unnecessary expenses and may be more likely to be rewarded as a result of methodological requirements. Sharing only in savings which exceed the MSR is consistent with the design of the original PGP demonstration and would reduce the probability that shared savings are earned as a result of chance or lower pre-existing expenditure trends due to existing efficiencies, and not newly enhanced care coordination and/or redesigned delivery of care. Further, such a requirement would encourage ACOs to strive to generate greater levels of savings.

A third option we considered would be to require all ACOs to exceed the MSR to be eligible for savings, but only to share savings in excess of a certain threshold. ACOs meeting certain criteria could be exempted from this provision and allowed to share in first dollar savings. This option would balance the need to have assurance that savings are not a result of random variation with the need to provide critical financial support for under-funded ACOs, particularly ACOs that serve a smaller population, safety net providers, or physician-only ACOs. Additionally, we have experience with this model through the PGP demonstration.

For the one-sided model, we proposed the third option, that once an ACO has surpassed its MSR, the ACO would share in savings beyond a certain threshold. We further proposed that, unless exempted, ACOs that exceed the MSR would be eligible to share in net savings above a 2 percent threshold, calculated as 2 percent of its benchmark (updated according to statute). The sharing rate would be applied to net savings above this 2 percent threshold in order to determine the shared savings amount. We believed that this threshold would protect the program from sharing unearned savings by helping to ensure that shared savings are due to enhanced care coordination and quality of care on the part of the ACO.

As previously discussed, many smaller physician-driven ACOs and ACOs caring for underserved populations have the potential to improve the quality and efficiency of care, but may be especially challenged in accessing capital to meet their needs. We hope to encourage successful participation by these ACOs in the Shared Savings Program. Additionally, we acknowledge that providers/suppliers working in these environments face additional challenges in coordinating care and creating the infrastructure necessary to create a successful ACO, and therefore may not be equipped to assume the risk of the two-sided model right away (and be

eligible for greater reward). Accordingly, we proposed that ACOs that met certain criteria outlined in the proposed rule (76 FR 19613) would be exempt from the 2 percent net savings threshold and would instead share on first dollar savings under the one-sided model.

For the two-sided model, we proposed that ACOs which generate savings that exceed the MSR would be eligible to share in savings on a first dollar basis. We indicated that a number of factors favored allowing two-sided model ACOs to share on first dollar savings. First, savings generated by ACOs assuming risk of losses are less likely to result from random variation compared to savings generated by ACOs under the one-sided model because these ACOs have a greater incentive to make the types of changes that are necessary to achieve shared savings and avoid shared losses. Second, sharing first dollar savings with two-sided model ACOs would provide greater reward for ACOs that choose to participate in the program's two-sided model as compared to the one-sided model. Therefore, under the two-sided model, the final sharing rate would be applied to an ACO's total savings against its updated benchmark.

Comment: Overall, comments expressed concern over the proposal for ACOs under the one-sided model, other than those exempted, to share savings net a 2 percent threshold once they exceed the MSR. Many commenters requested removal of the net 2 percent sharing rate. Most recommended sharing on a first dollar basis for all ACOs. Commenters provided a variety of rationales to support eliminating this requirement, for example, that it unduly increases uncertainty that an ACO will share in savings or could impede an ACO's ability to make the kinds of up front and ongoing investments needed to better manage care. Some suggested that adequate controls are already proposed to ensure that shared savings are due to improved care coordination and quality of care. Several commenters recommended first dollar sharing indicating random variation in data can work in both directions: Setting higher thresholds may protect CMS from random variation, but does not protect against or recognize random variation that might affect providers negatively.

Others suggested that first dollar sharing for all ACOs would encourage increased participation in the program, for instance helping ensure ACOs receive a return on investments. One commenter pointed out a 2 percent net sharing requirement was not included in the PGP demonstration. Another commenter questioned whether the 2 percent savings threshold is authorized by the law.

Commenters suggested several alternatives to the proposed 2 percent net savings threshold; most commonly, to allow first dollar sharing for the entire agreement period, or as one commenter suggested, for a portion of the agreement period. Another commenter suggested allowing ACOs, not CMS, to share 100 percent of the first 2 percent of savings earned, thereafter CMS and the ACO should receive their percentage shares.

Response: We are persuaded by comments suggesting the elimination of the 2 percent net sharing rate. Commenters made it clear that the option we proposed would unlikely achieve the balance we sought between a threshold low enough to ensure participation while protecting the Trust Funds from paying ACOs for results based on random variation. Commenters persuaded us that the 2 percent net sharing threshold could deter participation. We believe sharing on a first dollar basis with all ACOs will be important for encouraging participation and ensuring ACOs receive capital to invest in achieving the program's goals and achieve a return on investment. First dollar sharing, compared to alternatives that would share on a lower threshold amount, appears the most effective way to ensure ACOs receive needed capital. At this time, we consider other program protections—in particular the minimum savings rate—should be adequate to ensure shared savings result from ACO performance rather than random variation. We will monitor this issue, however, and could consider adjustments through future rulemaking should they be found necessary.

We are revising our proposal to allow for sharing on first dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR. We are finalizing our proposal to similarly allowing sharing on a first dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.

Comment: Commenters were generally supportive of the proposed exemption from the 2 percent net sharing threshold for small ACOs, particularly those in underserved and rural areas. A number of commenters suggested expanding the exemption to other types of ACOs. One, for example, recommended that the exemption include ACOs that treat a large proportion of dual eligible beneficiaries.

However, several commenters expressed concerns about the proposed exemption. One commenter explained that based on the proposed assignment methodology, ACOs that include FQHCs and RHCs would have difficulty meeting the threshold level to qualify for the exemption. Another commenter suggested the exemption may not be sufficient to encourage participation by ACOs in rural areas.

Response: Our elimination of the 2 percent net sharing rate negates the need for an exemption from this requirement. Accordingly, we are eliminating the proposed exemption from the 2 percent net sharing rate as all ACOs that achieve savings in excess of their MSR will share in savings on a first dollar basis.

Final Decision: We are revising our proposal under § 425.604 to allow for sharing on first dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR. We are finalizing our proposal under § 425.606 similarly allowing sharing on a first dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.

(5) Performance Payment Limits

Section 1899(d)(2) of the Act requires the Secretary to ''establish limits on the total amount of shared savings that may be paid to an ACO * * *.'' Therefore, in the proposed rule we addressed the issue of the maximum performance payment an ACO may receive in any given performance year. In determining what would constitute an appropriate limit, we stated that it should provide a significant opportunity for ACOs to receive shared savings generated from quality improvements and better coordination and management of Part A and B services, while avoiding creating incentives for excessive reductions in utilization which could be harmful to beneficiaries. Under the PGP demonstration, the limit was set at 5 percent of the organization's Part A and Part B expenditure target.

For purposes of the Shared Savings Program, we considered an option to vary the performance payment limit by the readiness of the ACO to take on greater responsibility and performance-based risk. ACOs seeking to participate in the Shared Savings Program will vary with respect to their readiness to function under a risk model due to their organizational and systems capacity and structure. Accordingly, some ACOs might more quickly be able to demonstrate quality improvements and savings than will others. Applying differential payment limits based on an ACO's readiness to take on performance-based risk could be another means to encourage and reward successful ACO participation.

In light of our experience with the PGP demonstration, we considered a limit of 5 percent of benchmark expenditures. We also considered whether a higher limit, such as 10 percent or 15 percent, would be appropriate to provide an even stronger incentive for ACOs to develop the quality and efficiency improvements that could result in greater shared savings. Depending on an ACO's composition, shared savings payments under such higher limits could represent an even larger portion of Medicare payments to ACO participants for care furnished to assigned beneficiaries since the limit is a percentage of the ACO's benchmark for Medicare Part A and B expenditures for assigned beneficiaries, which reflects all care furnished to those beneficiaries, regardless of whether it was provided in the ACO. For example, an ACO that does not include a hospital would have the opportunity to realize a relatively higher proportion of shared savings as a percentage of its Medicare revenue by reducing Part A expenditures for its assigned beneficiaries. However, opportunities to earn greater savings could also raise questions about whether the quality of care is improving, which is as important a goal as achieving savings in the Shared Savings Program. In the proposed rule, we recognized that providing an incentive for ACOs to invest to improve quality and efficiency of care needs to be balanced against providing an overly large incentive such that an ACO may be encouraged to generate savings resulting from inappropriate limitations on necessary care. A higher limit on total shared savings could provide such an incentive to limit care. While all ACOs may have this incentive to some degree, ACOs without Part A providers could have greater incentive to do so, depending on where the limit is established.

A lower limit, such as the 5 percent limit under the PGP demonstration, would reward ACOs for improving quality and efficiency and potentially generate more savings for the Medicare program without creating incentives to limit care that is appropriate and necessary. On the other hand, a lower limit might be an insufficient incentive for some potential ACOs to participate in the program. In contrast, a higher percentage limit, such as 10 or 15 percent of an ACO's Part A and B expenditure benchmark, would provide greater incentives for organizations to participate in the program and to achieve the quality and efficiency gains that are the goals of the Shared Savings Program. Many health care researchers believe that the rate of unnecessary health care is more than the approximate 10 percent which would be implied by establishing a 5 percent limit on ACO shared savings. (Since the maximum shared savings potentially realized by an ACO under the proposed one-sided model was 52.5 percent, we noted that a 7.5 percent limit on the ACO share would imply an expectation that overall savings may be as high as approximately 14 percent; a 10 percent limit would imply a savings expectation of approximately 19 percent.) On the other hand, a higher limit might provide some incentive for ACO providers/suppliers to reduce utilization inappropriately, which could potentially be harmful to beneficiaries.

In the proposed rule, we acknowledged that the considerations in favor of both a lower (for example, 5 percent) and a higher (for example, 10 percent) limitation on shared savings with an ACO had merit. Accordingly we proposed to establish the payment limit at 7.5 percent of an ACO's benchmark for the first 2 years of the agreement under the one-sided model. Following suggestions by MedPAC, and in order to encourage ACOs to assume performance-based risk and participate in the two-sided model, we proposed, for the two-sided model, to establish the payment limit at 10 percent of an ACO's benchmark for those ACOs that either elect the two-sided model initially for all 3 years or are transitioned from the one-sided model during the third year of their agreement period. (Since the maximum shared savings potentially realized by an ACO under the proposed two-sided model was 65 percent, a 10 percent limit on the ACO share would imply an expectation that overall savings may be as high as approximately 15 percent). We solicited comment on these proposed payment limits and on whether a higher limit—for example, 10 percent for all ACOs—would be more appropriate in light of the considerations discussed in the proposed rule and other considerations that commenters might wish to raise. We also sought comments on whether differential limits should be established based on an ACO's readiness, as discussed previously, including the criteria we would apply and the methods by which we would assess readiness and how differential limits should be structured. We stated that we would consider this information and the implications for a differential limit based on ACO readiness in future rulemaking cycles.

We stated that, regardless of what limit was adopted in the final rule, we planned to monitor beneficiary access to and utilization of services, and the potential contribution of the performance limit to any inappropriate reductions in services. Our final policies related to monitoring and addressing ACO performance are discussed in section II.H. of this final rule. Furthermore, we indicated that as we gain more experience with the Shared Savings Program and are able to evaluate how well the incentive structure under the Shared Savings Program is operating to generate greater quality and efficiency without inappropriately reducing utilization of services, we may undertake additional rulemaking to revise the performance payment limits we establish in this final rule.

Comment: One commenter suggested that limiting savings is reasonable if losses are also limited, in line with our proposal. Many commenters, however, opposed the proposed limits on shared savings for both the one-sided and two-sided models stating that these policies could limit the ACO's return on investment and therefore the attractiveness of the program, particularly given the large startup and operating costs ACOs are expected to face. One commenter cited a recent New England Journal of Medicine editorial which suggested the ACO must see a 20 percent gain in order to see a return on investment and noted that the proposal limits gains to 7.5 percent. Others suggested the limits could serve as a disincentive for ACOs to invest in transformational improvements, questioning the use of limits if the opportunity for shared savings is indeed a motivator for cost management behavior. One commenter explained that CMS' rationale for the limits, to prevent providers and suppliers from inappropriately reducing utilization, is unfounded; suggesting that the proposed quality performance standards and other proposed protections will effectively prevent ACOs from attempting to improperly reduce utilization of services. Another commenter suggested removal of the limits would signal CMS' commitment to the success of the program. Commenters indicated confusion about whether the limit applies only to the savings paid to the ACO or to the total savings subject to sharing.

Commenters typically recommended eliminating the limits, to allow ACOs to share in all savings they could achieve, suggesting this change could result in increased interest and participation in the program, particularly by smaller medical practices and oncologists. Other

commenters suggested raising the limits, for instance—

- Raise the limit to 10 for the one-sided model;
- Raise the limit by 5 percent for both the one-sided and two-sided models;
- Raise the limit to 15 or 25 percent; or
- For the two-sided model, incrementally increase the limit across the agreement period from 7.5 percent in year 1, to 10 percent in year 2 and 15 percent in year 3 to incentivize formation of ACOs willing to pursue this option.

Response: To clarify, the sharing limit applies to the savings paid to the ACO, not to the total savings subject to sharing. We are, however, persuaded by comments suggesting the importance of raising the performance payment limits to encourage participation and to ensure ACOs receive capital to invest in achieving the program's goals and achieve a return on their investment. We believe retaining the performance payment limits is necessary to comply with the statute and important for ensuring against providing an overly large incentive that may encourage an ACO to generate savings through inappropriate limitations on necessary care. We believe that a modest increase in the performance payment limits balances our concerns while increasing the attractiveness of the program. Further, we believe it is important to maintain a higher limit for ACOs accepting risk for losses, to incent participation in the program's two-sided model. Accordingly, we are modifying our proposal in order to provide a 10 percent payment limit for ACOs under the one-sided model and a 15 percent payment limit to ACOs under the two-sided model.

Final Decision: We are revising our proposal under § 425.604 and § 425.606 to raise the payment limit from 7.5 percent to 10 percent of an ACO's updated benchmark for ACOs under the one-sided model and to raise the payment limit from 10 percent to 15 percent of an ACO's updated benchmark for ACOs that elect the two-sided model.

f. Calculating Sharing in Losses

The proposed rule outlined the methodology for determining shared losses. We proposed a shared losses methodology that mirrored the shared savings methodology, comprised of: a formula for calculating shared losses based on the final sharing rate (1 minus the final sharing rate), use of a minimum loss rate (MLR) to protect against losses resulting from random variation and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay. We noted that under this approach, an ACO's share of losses would vary depending on its quality score. Therefore, an ACO with a higher quality score would owe a lower amount of losses compared to an ACO with an equivalent amount of losses but a lower quality score. We considered other approaches to calculating the amount of shared losses, tracking the options considered for establishing the quality standard. For instance, we considered using a threshold approach to measuring quality performance for purposes of determining the amount of shared savings and losses. Alternately we considered using a blend of these two methods, whereby we would allow ACOs to increase their share of savings with higher quality scores, but use a threshold approach when calculating losses. We sought comment on these options.

Comment: We received few comments on our methodology for calculating shared losses. One commenter explained that the elements of the shared savings and losses models need not be symmetrical.

Response: We are finalizing our proposed methodology for determining shared losses, mirroring the methodology for calculating shared savings. Our final policy on each specific issue is described in detail later in this final rule.

Final Decision: As proposed, the shared losses methodology under § 425.606 will mirror the shared savings methodology, comprised of: a formula for calculating shared losses based on the final sharing rate, use of a MLR to protect against losses resulting from random variation and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay.

(1) Minimum Loss Rate

We proposed a minimum loss rate (MLR) for purposes of computing shared losses when an ACO's actual expenditures exceed its benchmark. We explained that, as with savings, losses must exceed some minimum percentage around the benchmark in order to provide sufficient confidence that the losses experienced during a given performance year are not simply the result of random variation. We proposed the MLR would be the equivalent of the MSR under the two-sided model: A flat 2 percent regardless of the size of the ACO's assigned population. ACOs with excess expenditures below the MLR would not be responsible for repaying Medicare. ACOs with expenditures exceeding the MLR would be responsible for paying a share of excess expenditures calculated by multiplying the amount of excess above the updated benchmark by one minus the final sharing rate. Further we proposed that once the MLR was exceeded, ACOs would be responsible for paying the percentage of excess expenditures, on a first dollar basis, up to the proposed annual limit on shared losses.

Comment: Several commenters urged CMS to apply an adjustment for normal variation for losses, instead of requiring first dollar loss sharing. Some commenters favored policies that would exempt some ACOs from repaying losses, such as high quality performers. One commenter favored increasing the MLR and implementing a sliding scale so that the rate would correspond with the ACO's population size. Others favored lowering the MLR (for example, to 1 percent, as proposed for the Pioneer Model ACOs) or eliminating it altogether. One commenter explained that reducing or eliminating the MSR and the MLR recognizes that random variation works in both directions and over the course of the agreement period would likely have a net neutral effect on ACO revenues; further, this would be consistent with other inducements being offered to ACOs willing to bear risk immediately. One commenter appears to have confused the 2 percent MLR under the two-sided model with the 2 percent net sharing requirement under the one-sided model.

Response: We are finalizing our proposal to use a MLR in computing an ACO's shared losses. We believe that comments reflect confusion about the function of the MLR, which serves as a protection for ACOs. An ACO is not accountable for losses if its expenditures are lower than the MLR. This protects ACOs against being held accountable for losses that result from random variation, as opposed to their performance. If an ACO's actual expenditures are 2 percent or more above its updated benchmark, the ACO would be responsible for paying excess expenditures calculated by multiplying the amount of the excess above the updated benchmark by one minus the final sharing rate, up to the limit on shared losses. Once losses meet or exceed the MLR an ACO would be required to repay losses on a first dollar basis. To clarify, the MLR is distinct from, and unrelated to, the 2 percent net sharing threshold proposed for the one-sided model, which would have precluded ACOs from sharing savings on a first dollar basis.

The proposed 2 percent MLR appears to be an appropriate compromise between commenters' suggestions.

Exempting ACOs from accountability for losses under the two-sided model would negate the purpose of a risk-based payment arrangement. Eliminating or reducing the MLR may deter participation by some ACOs in the two-sided model, particularly those new to risk-bearing, in addition to potentially holding ACOs accountable to losses resulting from random variation.

Final Decision: We are finalizing our proposal under § 425.606 to apply a MLR for the two-sided model. To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must exceed its updated benchmark costs for the year by at least 2 percent. Once losses meet or exceed the MLR, an ACO would be responsible for paying the percentage of excess expenditures, on a first dollar basis, up to the proposed annual limit on shared losses.

(2) Shared Loss Rate

We proposed that ACOs with expenditures exceeding the MLR would be responsible for paying excess expenditures calculated by multiplying the amount of excess above the benchmark by one minus the final sharing rate. In the proposed rule we defined the final sharing rate as the quality performance sharing rate plus any percentage points for including FQHCs and/or RHCs as ACO participants.

Comment: We received a few comments on the proposed shared loss rate. One commenter suggested we allow ACOs the choice of a percentage shared loss rate (as proposed) or a fixed dollar amount of risk. Several commenters pointed out that under the proposed methodology for calculating shared savings and losses, an ACO could be accountable for a 100 percent share of losses (for example, if the ACO's quality sharing rate is zero) which is asymmetrical with the shared savings methodology. One commenter suggested that CMS ensure that the ACO's financial risk equals its potential gains in shared savings.

Response: We are maintaining our proposal to calculate the shared loss rate as one minus the final sharing rate. Given our elimination of the incentive for an ACO to include FQHCs or RHCs as ACO participants, the final sharing rate is based solely on quality performance. Therefore, under the two-sided model an ACO could achieve a maximum sharing rate of 60 percent based on quality performance. We believe that commenters identified an important concern about the shared loss rate, that an ACO could achieve a 100 percent shared loss rate, while the maximum shared savings rate is set at 60 percent. We are concerned that the prospect of a shared loss rate bounded at 100 percent could significantly deter participation by ACOs in the two-sided model, particularly ACOs that are new to the accountable care model and to risk-bearing. On the other hand, we do not want to limit the shared loss rate so much as to dampen the benefit of the program for Medicare or to remove the incentive for ACOs to strive for high quality scores. To balance these issues, we are modifying our proposal to cap the shared loss rate at 60 percent, to align with the maximum shared savings rate based on quality performance under the two-sided model.

Final Decision: As proposed, under § 425.606, the shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark will be determined based on the inverse of its final sharing rate based on quality performance (that is, 1 minus the shared savings rate). However, we are modifying our original proposal to provide that an ACO's shared loss rate will be subject to a cap of 60 percent consistent with the maximum rate for sharing savings.

g. Limits on Shared Losses

We proposed an annual maximum shared loss limit measured as a percentage of the benchmark to provide a greater incentive for organizations to participate in the Shared Savings Program under the two-sided model. We proposed to phase in the limit on shared losses over a 3 year period, with limits of: 5 percent, 7.5 percent, and 10 percent, respectively across the first 3 years for Track 2 ACOs. We further proposed that an ACO in Track 1 that has entered the third year of its initial agreement period would be liable for an amount not to exceed the percentage for the first year of the two-sided model, that is, shared losses would not exceed 5 percent of its updated benchmark.

Comment: Several commenters agreed with the proposed limits on shared losses, which one commenter indicated would provide an incentive for ACOs to participate in the two-sided model. One commenter explained that the limits on shared losses need not be symmetrical with the shared savings limit. Several commenters suggested alternatives, such as use of risk corridors and capped losses similar to the MA program, or limiting shared losses to 5 percent of the benchmark in all 3 years. Another commenter suggested using a per-beneficiary cap on losses. One commenter requested that CMS provide actuarial data to justify the proposed limits on shared losses.

Response: We are maintaining our proposal to phase in limits on shared losses, measured as a percentage of the ACO's updated benchmark, over the agreement period as follows: 5 percent, 7.5 percent, and 10 percent, respectively across the first 3 performance years for Track 2 ACOs. We believe the proposed limits 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.

Otherwise, we believe commenters' concerns are addressed by policies discussed in other parts of this finale rule. For instance, because we will truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile as determined for each benchmark year, we are adopting a de facto limit on the amount of shared losses an ACO can incur for care furnished to a single beneficiary.

Final Decision: We are finalizing our proposal under § 425.606 that the amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark: 5 percent in the first performance year of participation in a two-sided model under the Shared Savings Program, 7.5 percent in the second performance year, and 10 percent in the third performance year. Further, because we have eliminated the requirement for ACOs under the one-sided model to accept risk in their third performance year, we are not finalizing the proposed provision regarding the limits on shared losses for ACOs transitioning from the one-sided to two-sided model.

h. Ensuring ACO Repayment of Shared Losses

As we discussed in the proposed rule, ensuring that ACOs entering the two-sided model will be capable of repaying us for costs that exceed their benchmark is a critical program requirement. We described examples of financial protection requirements for other entities with which CMS does business.

We proposed a flat 25 percent withholding rate that would be applied annually to any shared savings payment earned by the ACO. We proposed that this withholding would serve as a component of the repayment mechanism that ACOs would need to establish to ensure their ability to repay Medicare for incurred losses. We

proposed that we would apply the withheld amount towards repayment of an ACO's losses. However, we recognized that the 25 percent withholding of shared savings may be inadequate to cover the total amount of shared losses, particularly if an ACO participating in the two-sided model experienced losses in its first year.

In order to more fully ensure that the Medicare program would be repaid in the event that an ACO incurred losses, we proposed that an ACO must demonstrate that it has established a self-executing method for repaying losses to the Medicare program. A detailed discussion of these methods is found in our April 7, 2011 proposed rule (76 FR 19622).

The intent of the proposal was to assure operational simplicity without establishing eligibility requirements that might discourage ACOs with limited risk-bearing experience from entering Track 2. Further, this option offered greater flexibility to ACOs in establishing their repayment mechanism compared to another option we considered, requiring ACOs to use only one of these repayment mechanisms. In that regard, we considered requiring ACOs to obtain a letter of credit in an amount not less than the maximum potential downside exposure for the ACO in any given performance year (for example 5 percent of the benchmark in the first performance year for an ACO entering Track 2, or for a Track 1 ACO entering its third performance year of its initial agreement period).

In the proposed rule, after considering several options for determining the adequacy of an ACO's recoupment mechanism, we proposed that the repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of per capita expenditures for assigned beneficiaries from the most recent year available. We believed that requiring ACOs to demonstrate their ability to repay losses at a level below the annual loss sharing limit was potentially equally effective as requiring ACOs to demonstrate their ability to repay the maximum amount of possible losses, but less onerous and also accounted for the limited probability that an ACO would incur the maximum possible losses.

Given the anticipated variation in ACO composition and regional variations in cost, we indicated that we believed the sufficiency of the ACO's repayment mechanism would need to be periodically reassessed to ensure its adequacy.

We further proposed that we would determine the adequacy of an ACO's repayment mechanism prior to its entrance into a period of participation in the Shared Savings Program. We also proposed that an ACO must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it accepts risk, to ensure that it is adequate to cover the anticipated number of assigned Medicare beneficiaries. Under the proposal, an ACO would have been required to maintain this repayment mechanism, ensuring adequate capitalization of funds in the case of some recoupment methods (such as adequately funded escrow accounts or reinsurance coverage), for the duration of the performance year and up until the time when we would need to be reimbursed for any losses by the ACO. We proposed that we would ensure that an ACO maintains an adequate repayment mechanism through monitoring activities.

We further proposed that an ACO would be required, as part of its application, to submit documentation of such a repayment mechanism for approval by us. This documentation would include details supporting the adequacy of the mechanism for repaying the ACO's maximum potential downside risk exposure. An ACO applying for the two-sided model would be required to submit this documentation as part of its initial application. An ACO applying for the one-sided model would also be required to submit this documentation as part of its initial Shared Savings Program application because under the proposal these ACOs would have been required to transition to the two-sided model in their third performance year.

To the extent that an ACO's repayment mechanism does not enable us to fully recoup the losses for a given performance year, we proposed to carry forward unpaid losses into subsequent performance years (to be recouped either against additional financial reserves, or by offsetting shared savings earned by the ACO).

We invited comment on these proposals and on the other options that we had considered.

Comment: A number of commenters expressed concern about the proposed requirement that ACOs establish a self-executing repayment mechanism to cover potential losses. While some of these commenters acknowledged CMS' desire for assurances regarding an ACO's ability to repay losses, they believed that the proposals were too burdensome and would place the ACOs in a difficult financial position. One commenter opposed requiring ACOs to establish a self-executing method for repaying losses, particularly as it may be imposed on individual providers that may lack a choice as to whether to join an ACO based on their relationship with a hospital or health system. This commenter did not believe such physicians should be required to pay for losses. Another commenter suggested that ACO providers and suppliers should bear financial risk proportional to the efficiency of their practice (for example, psychiatrists would bear a lower level of risk). Another commenter mentioned the burden a letter of credit would create for providers and expressed distaste for the mandatory withhold. Several commenters generally expressed doubt that the proposed requirement would ensure that ACOs would be able to repay potential losses.

Others provided comments about the financial burden of the proposed repayment mechanisms, particularly for smaller ACOs that may be unable to meet the solvency requirements. They indicated that it would be very difficult, if not impossible, for ACOs, which would typically include low margin businesses, to be at risk for both the administrative costs associated with forming and operating an ACO and also be subject to underwriting losses. These commenters viewed the proposed 1 percent repayment mechanism as an additional drain on ACOs participating in the Shared Savings Program and therefore recommended that the requirement be removed.

A number of commenters expressed concern about reinsurance as a repayment option. One commenter suggested that reinsurance would be costly and would reduce or eliminate any net payment available to reward the ACO providers/suppliers. This commenter believed that a significant increase in the sharing percentage and the limit on shared savings would be required to make reinsurance a viable repayment approach. Other commenters asked that CMS clarify in the final rule the mechanisms for ACOs to obtain reinsurance. A couple of commenters encouraged CMS to specify a clear mechanism in the final rule for ACOs to obtain reinsurance, such as CMS sponsorship of reinsurance pools for ACO providers or including additional funds in the shared savings payments to ACOs. One commenter suggested that we require ACOs to obtain insurance only from highly rated, State regulated insurance carriers.

Several commenters suggested eliminating the proposed requirement for a repayment mechanism, given the proposed 25 percent withhold, believing it was unnecessary to have both

requirements. On the other hand, as described later in this final rule, a number of other commenters requesting elimination of the proposed 25 percent withhold cited the proposed repayment mechanism as providing sufficient coverage to protect CMS against losses. For example, a commenter indicated that CMS should monitor capital adequacy on an annual basis and rely on the provisions in the proposed rule regarding the requirement to adopt a self-executing repayment method, rather than a withhold, to ensure that ACOs will be able to repay losses to the program.

Some commenters suggested additional alternative approaches that CMS could consider to address concerns about an ACO's ability to pay for losses, for example:

- Allow flexibility for an ACO to determine the magnitude of financial risk it will experience and to determine the most appropriate manner of repayment.
- Allow ACOs to use existing financing mechanisms, used to participate in two-sided models outside of Medicare, to ensure repayment of shared losses under the Shared Savings Program.
- Adjust the repayment method based on the ACO's prior year performance in the Shared Savings Program, or its performance and experience with other payers. One commenter suggested that CMS consider waiving or reducing the repayment mechanism requirements for applicants to the two-sided model, particularly those who have demonstrated experience in managing risk through participation in a Medicaid, State, or private ACO or other payment reforms. In this commenter's view, a track record of managing risk under other programs should reduce CMS' uncertainty regarding the financial viability of the ACO.
- Adopt certain other approaches used by some managed care companies.
- An agreement to recoup losses from future Medicare revenue payments should be required for on-going enterprises (those in existence for 5 or more years of continuous operations). The commenter suggesting this alternative further explained that the repayment term for any losses should be set on a sliding scale of time in proportion to the amount of debt as a percentage of assigned beneficiary per capita expenditures for the most current year results available.

Several comments raised concerns about how ACOs would share losses with their participants. One commenter indicated that liability for losses creates significant operational issues for ACOs and raised questions about how losses would be shared as follows:

- If losses are incurred, how would the liability for sharing those losses be shared?
- Will physicians and other professionals have incentives to participate if they know they may have out-of-pocket liability or would be required to accept Medicare payments at less than traditional Medicare payment rates?
- May the financial obligation for losses be disparately shouldered by ACO participants or ACO providers/suppliers and would this implicate the fraud and abuse laws?

One commenter indicated that recoupment efforts should be directed against the ACO and not its individual primary care physicians.

In addition, a few comments asked us to clarify specific points in the proposal. For example, one commenter simply asked that CMS further clarify the minimum capitalization requirement. Another asked whether there was a minimum reserve requirement, and if so what the amount would be. Another asked how we will evaluate if the proposed methodology and minimum amount are sufficient. Another asked how an ACO should calculate beneficiary assignment when preparing its initial application in order to ensure that the amount of reserves is accurate.

In response to the proposal to carry forward losses into future years, one commenter suggested that this provision should depend on the success of the overall program. As an example, the commenter suggested that if 50 percent or more of the ACOs entering the program under the one-sided model in 2012 see savings in years 1 and 2, then CMS should carry forward losses because there would be a likelihood of achieving savings in a future year. In contrast, if 75 percent or more of ACOs experience losses, then CMS should undertake a review of the entire program to evaluate if there is a fatal design flaw. Further, the commenter suggested that if an actuarial review finds that there are significant deviations from initial assumptions, then CMS should consider forgiving ACOs for any net losses that occurred during the initial 3 year period. Another commenter requested that CMS use its discretion to waive repayments in full or in part and to make other arrangements to address unpaid losses (aside from carrying them forward to the next year).

A few commenters expressed support for the proposed repayment mechanism. Several commenters urged more stringent protections; for instance, one commenter noted that the requirements that ensure an ACO could meet its risk obligation appeared weak in comparison to those for Medicare Advantage plans. Another commenter expressed concern that the financial failure of ACOs could undermine the solvency of physician practices, thereby limiting patient access to care in the ACO's locality and urged additional protections to ensure both ACO solvency and to safeguard beneficiaries, as opposed to just ensuring adequate funds for CMS to recoup losses.

Several commenters expressed support for proposed policies to ensure ACOs maintain an adequate repayment mechanism over time. For example, one commenter recommended that CMS maintain the rule's strong repayment proposals and further suggested that CMS should periodically reevaluate the adequacy of the various repayment mechanisms during the agreement period, believing that it is imperative for CMS to maintain strong solvency protections to protect the Medicare program and beneficiaries, and to counter efforts to shift cost risks to private payers. Another commenter expressed support for a process whereby CMS would, on an annual basis, verify that processes specified in the ACO's application had been implemented and that other program requirements had been satisfied.

Response: We continue to believe that it is a critical program requirement to ensure that ACOs entering a two-sided model are capable of repaying us for costs that exceed their benchmark. We agree with the commenters' concern that it is desirable to protect consumers from disruption of their care due to a financial failure of an ACO. We have experience implementing protections to guard against the financial failure of providers in other parts of the Medicare program. Our proposals took into account our experiences with these other programs and requirements. We further recognize that the Shared Savings Program is a unique, new Medicare program and we want to address commenters' concerns about the burdens of participating in this program to the extent possible. However, in light of a number of other significant changes to the original proposals for the program that we are making in this final rule in order to reduce the burdens for participating ACOs, we continue to believe our proposals to ensure that ACOs are able to pay for any shared losses are reasonable.

In particular, a number of commenters objected to the repayment proposals on the grounds that they were excessive in light of the additional requirement of a

25 percent withhold from shared savings. As discussed in section II.G.2. of this final rule we are not finalizing our proposal to require a withhold of shared savings as a method for helping assure that ACOs could repay any future shared losses.

Another significant change from the proposed rule which we have included in this final rule (discussed in section II.G.1. of this final rule) is that Track 1 of the program is now a one-sided only model (that is, shared savings only) for the entire initial agreement period. During the term of the initial agreement, only those ACOs that voluntarily choose to participate in the Shared Savings Program in the two-sided model under Track 2 will be subject to the repayment rules. We would expect that during the initial stages of the program, these Track 2 ACOs would more likely be larger and/or more experienced ACOs, and thus have the experience, expertise, and/or resources to meet the repayment requirements.

After review of the comments, we are finalizing our proposal to allow ACOs flexibility to specify their preferred method for repaying potential losses, and how it would apply to the ACO participants and ACO providers/suppliers. We continue to believe our proposal provides significant flexibility for ACOs to identify the repayment method that is most appropriate for their organizations. As a result, our policy as proposed, already affords ACOs, particularly smaller ACOs, the choice of the alternative that would be least burdensome for them. For example, larger ACOs that include hospital systems may be able to repay losses from their reserves, whereas, smaller ACOs may prefer to pay for shared losses through reductions to their future FFS payments. Under the approach we are finalizing, during the application process and annually, each ACO participating in Track 2 will be required to demonstrate that it has established a repayment mechanism. As part of this, individual ACOs must specify how the liability for sharing losses would be shared among ACO participants and/or ACO providers/suppliers. We will determine the adequacy of an ACO's repayment mechanism prior to the start of each performance year under the two-sided model.

In this final rule, we are also finalizing our proposal that the minimum amount of the reserves required for an ACO is sufficient to ensure repayment of potential losses equal to at least 1 percent of per capita Medicare FFS Parts A and B expenditures for its assigned beneficiaries. Further, we are clarifying that this amount should be based either on expenditures for the most recent available performance year or benchmark year. We continue to believe this is a reasonable amount that reflects our desire to balance possible financial burden on ACOs with our need for a reasonable assurance that any shared losses could be paid. For example, Track 2 ACOs could be responsible for losses up to a maximum of 5 percent of its benchmark in performance year 1, 7.5 percent in performance year 2, and 10 percent in performance year 3. We believe requiring a reserve of 1 percent is reasonable relative to this level of liability.

We decline to finalize the proposed policy to carry forward losses into future program years (as suggested by one commenter). We believe the final rule includes sufficient protection against ACOs which fail to repay their losses, including the requirement for an ACO to establish a repayment mechanism, and program protections which would allow CMS to terminate an ACO for not fully repaying its losses with the opportunity for the ACO to enter into a corrective action plan to address this failure to meet program requirements.

In addition, as requested by a commenter, we will continue to monitor the program as it is implemented to determine whether program adjustments are needed.

Further, because we will allow ACOs to participate in a shared savings only model for their first agreement period, we are revising our proposal to require only ACOs entering the program's two-sided model (Track 2) or requesting an interim payment under the one-sided model (Track 1) to demonstrate an adequate repayment mechanism.

We are not adopting the comments that suggested a government sponsored reinsurance option, such as CMS-sponsored reinsurance pools for ACOs. ACOs that might want to pursue reinsurance as a repayment mechanism should contact insurers in their individual States to further explore this option.

We are also not adopting other comments that encouraged us to adopt approaches employed by other payers, or to adjust the repayment method based on prior year performance in the Shared Savings Program or performance and experience with private payers. At this time we do not believe such approaches would be feasible since, for example, we would not have readily available information or evaluation criteria about such performance. As explained previously, we believe the 1 percent reserve requirement provides a reasonable balance between minimizing the financial burdens on ACOs, while providing an assurance to the Medicare program that any shared losses will be repaid.

We will further clarify operational questions about the repayment requirement through the application process and other program instructions. Finally, we note that the commenters' concerns that the division of liability for losses among ACO participants and ACO providers/suppliers may implicate certain fraud and abuse laws, except to the extent that those laws are waived.

Final Decision: In this final rule we are retaining our proposed policies under § 425.204 concerning the repayment mechanism to ensure ACO repayment of shared losses. We are finalizing our proposal to allow ACOs flexibility to specify their preferred method for repaying potential losses, and how that would apply to ACO participants and ACO providers/suppliers. During the application process and annually, each ACO under the two-sided model will be required to demonstrate that it has established a repayment mechanism. One-sided model ACOs requesting interim payment must make a similar demonstration at the time of application. We will determine the adequacy of an ACO's repayment mechanism prior to the start of each year under the two-sided model. We are also finalizing our proposal that the repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of total per capita Medicare Parts A and B fee-for-service expenditures for assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark. To the extent that an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, CMS will not carry forward unpaid losses into subsequent performance years and agreement periods.

i. Timing of Repayment

We proposed that an ACO must make payment in full to CMS of any shared losses within 30 days of receipt of notification of the shared losses.

Comment: Commenters requested that we consider extending this deadline, for example to 60 or 90 or 120 days, stating this would be a more reasonable timeframe given capital restraints on some ACOs. Several commenters suggested offering ACOs the option of paying losses in installments.

Response: In developing the proposed rule, we considered repayment within 30 days to be a timeframe which would benefit ACOs because shared losses would be considered overpayments and under sections 1815(d) and 1833(j) of the Act would begin to accrue interest if not paid within 30 days of the ACO's notification of losses. We appreciate commenters' concerns about the burden that a 30 day requirement could pose to ACOs. We agree that ACOs, composed of many independent participants, may need additional time to gather the amount owed. Accordingly, to address these concerns, we will use our authority under section 1899(f) to waive the requirement under sections 1815(d) and 1833(j) that repayment be made within 30 days, and to extend the deadline for repayment and the date on which interest on shared losses owed by an ACO will start to accrue until 91 days after the ACO receives notification of shared losses. Thus, in order to avoid interest ACOs must make payment in full to CMS within 90 days of receipt of notification of shared losses. Given that commenters' suggestions for extending the repayment deadline ranged from 60 to 120 days, we consider 90 days an appropriate timeframe for ACOs to make the arrangements necessary to repay shared losses.

Final Decision: We are revising our proposed policies under § 425.606(h) concerning timing of repayment of losses. If an ACO incurs shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

j. Withholding Performance Payments

Over the course of its participation in the Shared Savings Program, an ACO may earn shared savings in some years and incur losses in other years. In the proposed rule, we considered the issue of whether the full amount of shared savings payments should be paid in the year in which they accrue, or whether some portion should be withheld to offset potential future losses. For example, under the PGP demonstration, a flat 25 percent withhold applied to annual earned performance payments to guard against losses in future years as well as to provide an incentive for PGPs to continue in the demonstration since the withhold was only released at the end of the demonstration period or when the PGPs were rebased. Under the two-sided model, we proposed that an ACO could use a withhold of its earned shared savings payment as one option for demonstrating an adequate repayment mechanism in the event it incurs shareable losses. We explained that the requirement that ACOs be willing to commit to completing a multiyear agreement to participate in the Shared Savings Program is necessary to ensure that the program achieves its long-term goal of redesigning health care processes, and our proposal to withhold performance payment was designed to reinforce that requirement. Since we wanted to encourage ACOs to participate for the entire term of their agreements, protect the Medicare program against losses, and ensure ACOs have an adequate repayment mechanism in the event they incur losses, we proposed that a flat 25 percent withholding rate would be applied annually to any earned performance payment. Under the two-sided model, we proposed that an ACO may withhold an additional portion of its earned performance payment as a way to demonstrate an adequate repayment mechanism in the event it should incur shareable losses. Furthermore, we proposed that at the end of each agreement period, positive balances would be returned to the ACO. However, if the ACO does not complete its agreement period, the ACO would forfeit any savings withheld.

Comment: Nearly all commenters opposed the proposed 25 percent withhold, suggesting that given the anticipated slow return on investment and potentially high startup and operating costs, it would adversely affect participation or pose financial hardship on ACOs by restricting necessary capital. As one commenter explained, the withhold may hinder ACO investment and reinvestment in infrastructure and program activities that may lead to further improvements in care and care delivery processes. Some commenters suggested the proposed withhold poses a barrier to participation by smaller, rural, safety net, and physician-only ACOs. One commenter considered the need for capital support to be potentially crucial to participation by safety net providers given the proposed withhold. Other commenters suggested that the withhold appears to penalize only the best-performing ACOs while having no impact on poor performing ACOs.

Other commenters questioned the ability of the proposed policy to achieve its aim of protecting CMS against losses and indicated that other proposed protections, such as a self executing repayment mechanism sufficient to cover 1 percent of total per capita expenditures, are more than adequate. Several commenters suggested the withhold is inappropriate for organizations accustomed to managing risk. Others questioned the need for the withhold under the one-sided model, and noted in particular, that the proposed 2 percent net sharing rate may be sufficient to cover CMS' risk of not recovering losses when ACOs transition to the two-sided model. One commenter suggested CMS consider requiring ACOs to have reserves similar to under an insurance model to participate, rather than holding back earned savings.

Several commenters addressed the use of the withhold as a means to encourage full-term participation. One commenter noted this proposal creates a sense that CMS does not trust its provider partners. One commenter stated forfeiture of the withhold for failure to complete the 3 year agreement unfairly punishes ACOs that must withdraw from the program, for example ACOs whose population falls below the required 5,000 beneficiaries.

Commenters typically suggested eliminating the withhold entirely, suggesting it is redundant or unnecessary in light of other proposed requirements (such that ACOs demonstrate an adequate repayment mechanism at the time of application). Several commenters suggested that, at a minimum, the amount of the withhold be reduced, recommending that it not exceed 10 percent of shared savings. In some cases, commenters recommended a temporary reduction in the amount withheld. Several recommended allowing ACOs a choice between a withhold and demonstrating adequate financial reserves to repay losses. Several commenters suggested CMS pay interest on the withheld amount, or clarify in the final rule its intent to pay interest on this amount. Another commenter urged CMS to ensure alignment between the withhold of payment under the Shared Savings Program and the mechanism for repayment under the Innovation Center's potential Advance Payment initiative.

Several commenters suggested alternative policies for linking the withhold to ACO performance. For example, one commenter favored an alternative to the proposed method for calculating shared savings whereby CMS would also use a multi-year metric of savings. This commenter suggested CMS would withhold a portion of annual savings (similar to the proposed 25 percent withhold) and award a net performance payment at the end of the agreement period based on the multi-year metric. This approach could address concerns expressed by several commenters that ACOs may have a financial disincentive to perform high cost procedures or order laboratory tests involving substantial upfront costs, which over time result in improved

health outcomes or savings (such as bariatric surgery or lab tests that lead to better treatment decisions).

Response: We are persuaded by comments recommending elimination of the 25 percent withhold. While we continue to believe that strong mechanisms for repayment of potential losses are necessary, we have concluded that the withhold may be an ineffective mechanism for ensuring repayment of potential losses. As commenters point out, an entity that generates savings in the first or second year is also likely to generate savings in the third year. Therefore, the withhold could serve as a penalty for successful ACOs while doing little to protect the Trust Fund against underperforming ACOs. Further, we agree with the commenters that suggested that other aspects of the program may be sufficient to ensure ACOs repay losses. In particular, we are finalizing the requirement for ACOs to establish a self-executing repayment mechanism, under which ACOs could elect an annual withhold on savings as part of their repayment mechanism. Commenters also noted the potential unintended consequences of using the withhold to encourage ACOs to complete their agreement periods. We are especially concerned that the forfeiture requirement could punish ACOs terminated from the program for circumstances beyond their control. Lastly, we are concerned that the withhold could pose a financial hardship for ACOs by forestalling payment of funds that could support operational costs, and thus, the policy could be a potential barrier to the formation of ACOs.

A smaller withhold, as suggested by some commenters, would not effectively address the aforementioned concerns. Even a smaller withhold could penalize high-performing ACOs or those terminated from the program for legitimate reasons beyond their control and pose a barrier to participation. Further, while we appreciate commenters' concerns about the need for a multi-year measure of savings, to be implemented through a withhold of savings, we decline to implement this approach. We believe that other program requirements offer ACOs sufficient incentive to provide high quality, cost-effective and patient-centered care, while the program's monitoring provisions will enable us to detect ACOs' avoidance of necessary services.

Final Decision: We are revising our proposal to eliminate the 25 percent withhold and the related proposed provision concerning forfeiture of the 25 percent withhold in the event of early termination from the program.

k. Determining First Year Performance for ACOs Beginning April 1 or July 1, 2012

As discussed in Section II.C. of this final rule, we will offer start dates on April 1, 2012 (agreement period of 3 years and 9 months), and July 1, 2012 (agreement period of 3 years and 6 months) for those ACOs that apply and are approved to participate in the Shared Savings Program during 2012. This section describes the methodology for determining shared savings and losses for the first performance year for April 1 and July 1 starters defined as 21 and 18 months respectively. This methodology will consist of an optional interim payment calculation based on the ACO's first 12 months of participation and a final reconciliation occurring at the end of the ACO's first performance year. Such first year reconciliation, taking into account the 12 months covered by the interim payment period as well as the remaining 6 or 9 months of 2013, will allow us to determine the overall savings or losses for the ACO's first performance year.

As we have previously discussed, commenters expressed support for policies allowing for a shorter turnaround period for feedback on quality metrics and shared savings reconciliation. In particular, commenters stressed the importance of shared savings for establishing return on investment, and supporting ongoing operations and likewise achievement of program goals. We agree with commenters about the importance of timely availability of funds.

In this final rule, we are adopting a policy that will enable ACOs with start dates of April 1 and July 1, 2012 to opt for an interim payment calculation as part of their application to participate in the Shared Savings Program. However, ACOs opting for interim payment under either the Track 1 one-sided or Track 2 two-sided model will need to assure CMS of their ability to repay monies determined to be owed upon final first year reconciliation. For ACOs under the two-sided model, their demonstration of an adequate repayment mechanism as part of their entrance into a shared loss arrangement will be sufficient also to assure return of an overpayment of shared savings under the interim payment calculation. ACOs under the one-sided model would, likewise, need to demonstrate an adequate repayment mechanism. We will, therefore, require ACOs entering Track 1 with start dates of April 1 or July 1, 2012, that opt to receive interim payment calculation to demonstrate an adequate repayment mechanism as under Track 2 to repay any overpayment of shared savings. This requirement will not apply to Track 1 ACOs with start dates of April 1 or July 1, 2012, that do not elect interim payment calculation.

(1) Interim Payment Calculation

In the interim payment calculation, we will determine shared savings and losses based on the ACO's first 12 months of program participation. Quality performance will be assessed as described in section II.F of this final rule. Quality performance for the interim payment calculation will be based on GPRO quality data reported for calendar year 2012. (Claims-based and CAHPS measures will be calculated for informational purposes for 2012.) We believe that quality data based on CY 2012 is an appropriate measure of ACO's quality performance for determining interim payment because ACOs beginning April 1 and July 1 will have submitted GPRO data for CY 2012 as part of demonstrating their eligibility for the 2012 PQRS incentive.

The same methodology for determining shared savings and losses, as specified in section II.G. of the final rule will apply to this interim payment period. More specifically, we will apply the methodology as stated elsewhere in section II.E. of this final rule for assigning beneficiaries and in section II.G. of this final rule for determining shared savings and losses (including calculating and risk adjusting expenditures, establishing the MSR and MLR, and determining shared savings or losses) based on the ACO's first 12 months of performance with the exception of calculating the update to the benchmark. For purposes of interim payment calculation, the historical benchmark will be updated (and adjusted for changes in beneficiary risk as described below) for the period which includes the ACO's first 12 months of participation.

Depending on the results of the interim payment calculation, the ACO may receive a shared savings payment or, in the case of ACOs under the two-sided model, be liable for shared losses. ACOs will be notified of shared savings or losses. Unless stated otherwise, program requirements which apply in the course of a performance year apply to the interim payment period.

(2) First Year Reconciliation

For ACOs beginning April 1 or July 1, 2012, the reconciliation for the first performance year will occur after the completion of the ACO's first performance year, defined as 21 months

for April 1 starters and 18 months for July 1 starters; that is at the conclusion of CY 2013. First year reconciliation will account for the entire 18 or 21 month period. Our assignment methodology and calculations of the updated benchmark and performance year expenditures will take into account the overlap between the ACO's first 12 months of performance and CY 2013. To simplify the summation of performance year expenditures and the updated benchmark for the two overlapping timeframes, we will state figures for first year reconciliation in the aggregate, rather than on a per capita basis. Quality performance for first year reconciliation will be based on complete and accurate reporting, for all required quality measures, for CY 2013.

The following steps outline the methodology for adjusting the ACO's interim payment determination to account only for the 6 or 9 months included in CY 2012 and summing it with the ACO's CY 2013 performance:

- *Assignment:* First performance year expenditures will be summed over beneficiaries assigned in two overlapping 12 month assignment windows. The first window will be the beneficiaries assigned for the first 12 months used for interim payment calculation. The second window will be beneficiaries assigned for CY 2013.
- *Aggregate expenditures for the first performance year:* We will sum aggregate interim payment expenditure dollars to account for the ACO's first 6 or 9 months during CY 2012 for beneficiaries assigned for the interim payment calculation with aggregate dollars calculated for CY 2013 for beneficiaries assigned for CY 2013.
- *Risk adjustment:* Risk adjustment for beneficiaries assigned in CY2013 will be performed as it would be for a normal calendar performance year, based on a comparison of risk scores for continuously assigned and newly assigned beneficiaries to BY3 risk scores. We will identify beneficiaries from the CY 2013 assignment window as either continuously assigned or newly assigned relative to the previous calendar year. We will base risk adjustment for the 6 or 9 months of performance year one (PY1) that lie within CY 2012 on the same adjustment factor identified for purposes of the interim payment calculation. Respective risk adjustment factors will be used to adjust updated benchmark dollars to the performance year risk level.
- *Updating the benchmark:* We will establish an updated benchmark for the first performance year stated in aggregate dollars. Based on the assigned beneficiary population for the ACO's first 12 months of performance we will calculate the ACO's interim updated benchmark for the average fraction of expenditures incurred in the latter 6 or 9 months of CY 2012, and restate it in terms of aggregate expenditures. We will add to that an updated aggregate benchmark representing CY 2013.
- *Determining shared savings/losses:* We will determine the savings percentage for the entire 18 or 21 month performance year by comparing summed expenditures to summed updated benchmark dollars. We will compare this percentage to the ACO's MSR or MLR as stated in terms of a percentage. For ACOs under the one-sided model, we will compare the PY1 savings percentage to an MSR obtained from Table 6 by counting all beneficiaries who have been assigned in at least one of the two assignment windows for PY1. For ACOs under the two-sided model, we will compare the PY1 savings percentage to a flat 2 percent MSR or MLR.

The reconciled amount of the shared savings or losses owed to or by the ACO for the performance year will be net of any interim payments of shared savings or losses. CMS may determine that it owes the ACO additional shared savings payments or received an overpayment of shared losses from the ACO. Conversely, following the first year reconciliation, CMS may determine the ACO has been overpaid for shared savings or owes additional shared losses. In either of these cases, the ACO would owe CMS the difference. ACOs will be notified of shared savings or losses, or other monies determined to be owed upon first year reconciliation. Unless stated otherwise, program requirements which apply in the course of a performance year apply to the ACO's first year reconciliation.

(3) Repayment Mechanism for ACOs Electing Interim Payment Calculation

An interim payment system therefore raises a concern about the ability of an ACO to repay CMS in the event that first year reconciliation results in a payment due to CMS. As described previously, ACOs under the program's two-sided model must demonstrate that they have a self-executing mechanism for repaying losses equal to at least 1 percent of the ACO's Medicare fee-for-service Parts A and B total per capita expenditures for its assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark. However, as discussed in this section, the repayment mechanism would generally apply only to ACOs under the two-sided model.

We believe this same repayment mechanism is also sufficient to ensure that ACOs in the one- and two-sided models that opt for interim payments can repay CMS in the event that the ACO owes CMS money after first year reconciliation. ACOs must indicate in their application whether they are requesting an interim payment calculation. Therefore, similar to the requirements for two-sided model ACOs in this final rule, we will require those ACOs that choose to request an interim payment during their first performance year, regardless of Track, to demonstrate as part of their application that they have an adequate repayment mechanism in place.

Another issue raised by interim payments is the deadline for paying shared losses, as well as the deadline for refunding other monies determined to be owed by the ACO after first year reconciliation. As described previously in this final rule, ACOs under the program's two-sided model will be required to repay losses within 90 days of receipt of notification of losses. Therefore, to align the interim payment policy with our policy regarding payment of shared losses, we will require that any monies determined to be owed by the ACO after first year reconciliation must be repaid by the ACO, in full, within 90 days of receipt of notification.

Final Decision: We are adopting a policy under § 425.608 that will enable ACOs with start dates of April 1 and July 1, 2012 to opt for an interim payment calculation, to determine shared savings and losses, at the end of their first 12 months of program participation. Unless stated otherwise, the same methodology for determining shared savings and losses that applies under §§ 425.604 and 425.606 will apply to this interim payment calculation. For ACOs with start dates of April 1 or July 1, 2012, reconciliation for the first performance year will occur after the completion of the ACO's first performance year, defined as 21 months for April 1 starters and 18 months for July 1 starters. ACOs must indicate in their application whether they are requesting an interim payment calculation. ACOs that opt for interim payment during their first performance year must demonstrate as part of their application that they have an adequate repayment mechanism in place, consistent with the requirements for two-sided model ACOs in this final rule. ACOs that generate shared losses under the interim payment calculation must repay such losses within 90 days of notification of losses. Further, any monies determined to be owed by an

ACO after first year reconciliation, whether as a result of additional shared losses or an overpayment of shared savings, must be repaid to CMS, in full, within 90 days of receipt of notification.

3. Impact on States

In the proposed rule, we emphasized that, under our proposal for a two-sided model under the Shared Savings Program, the Medicare program would retain the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries, and that the agreement to share risk against the benchmark would be solely between the Medicare program and the ACO. We did not intend that any of our proposals concerning the Shared Savings Program would render States responsible for bearing any costs resulting from the operation of this program. However, we noted that each State has its own insurance and risk oversight programs and that some States may regulate risk bearing entities, such as the ACOs participating in the two-sided model under the Shared Savings Program. Accordingly, we sought comment on whether any of our proposals for the two-sided model in particular, or the Shared Savings Program in general, would trigger the application of any State insurance laws, the adequacy of those provisions that we have set forth, and the ways that we can work with ACOs and States to minimize the burden of any additional regulation.

Comment: A few commenters expressed concern that the two-sided model could trigger some State insurance laws, or that States could decide to subject ACOs under the program's two-sided model to State licensure requirements (for example, requiring the ACO to obtain an HMO license). In particular, a few commenters expressed concern about potential overlap between State insurance requirements and the proposed requirements to demonstrate an adequate repayment mechanism (including establishing lines of credit, recoupment of losses from future FFS payments, and obtaining reinsurance sufficient to account for 1 percent of per capita expenditures for the assigned beneficiaries).

A few other commenters were concerned that State laws may serve as a barrier to ACO formation due to the added expense of compliance with State regulation of ACOs. Several commenters requested clarification on or recommended Federal protection from these State laws, for instance by Federal preemption of State insurance laws, a safe harbor or otherwise discouraging assertion of authority by State insurance agencies over ACOs that participate in the Shared Savings Program. One commenter suggested CMS promote a uniform national privacy requirement to preempt potentially conflicting State laws, particularly surrounding quality, data use, information sharing, and privacy protections.

One commenter wanted CMS to ensure that States will ''not require ACOs to obtain an HMO license * * * to meet financial and repayment requirements''. On the other hand, several commenters explained that State licensed organizations that accept insurance risk must comply with strict financial solvency criteria, and were supportive of State regulation of ACOs. Another commenter suggested that ACOs that assume risk for losses and/or perform other health plan functions that are regulated at the State level (for example, subject to State financial and consumer protection standards) should have to meet the same standards required of health plans. These standards include financial requirements (for example, capital, reserve and solvency requirements); network requirements (for example, ensuring access to adequate numbers and types of providers); filing, reporting and disclosure requirements; and quality improvement requirements, including accreditation standards and other consumer protection standards. The commenter expressed a concern that if ACOs are not subject to the same standards as heath plans, then consumers receiving care from an ACO may have less access to care, receive care of lesser quality, be faced with increased costs, and/or be more vulnerable to discontinuation of coverage if unforeseen events occur, such as a flu pandemic or similar disaster impacting the health care system. One commenter suggested that the proposed 25 percent withhold and repayment mechanism may not be necessary for ACOs complying with State financial solvency requirements, but should be required for ACOs that are not licensed to assume both professional and institutional risk by the State in which they operate.

Several commenters asked that CMS address whether Federal laws would preempt State laws that might conflict with the intent of the regulation. One commenter stated that without such preemption there could be barriers to clinical integration. One commenter suggested that CMS provide a list of States that either currently recognize or authorize ACOs under their State laws, or have pending legislation to recognize ACOs.

One commenter expressed concern that this regulation would override State and local protocols concerning ambulance transportation. The commenter was concerned that ambulances would be required to deliver patients to ACO participants instead of the closest or most appropriate facility.

Another commenter recommended that ACOs be exempt from State malpractice laws so that the burden of malpractice insurance and litigation costs are not added to the already significant cost of forming and maintaining an ACO. This commenter did not believe such protections for ACOs would preclude patients from pursuing claims for malpractice against ACO participants or from seeking discovery directly from such participants under existing State laws.

Another commenter urged medical liability protections for physicians complying with ACO guidelines, such as criteria for utilizing diagnostic imaging. The commenter recommended the following approaches:

- Deem an ACO and/or ACO-participating physician to be an employee of the Public Health Service for purposes of any civil action that may arise from ACO-related services. The commenter stated that this approach would require patients alleging malpractice to pursue their claim under the Federal Tort Claims Act.
- Allow physicians to introduce the relevant ACO guidelines into evidence as an affirmative defense to any medical liability claim.
- Establish a standard of proof of clear and convincing evidence for any medical liability lawsuit in which a physician utilized ACO guidelines.

Another commenter suggested that CMS structure the program to be flexible enough to facilitate State and local initiatives.

Finally, a commenter, reported that its State department of insurance indicated that the proposed rule does not implicate any State insurance laws.

Response: In the proposed rule we did not make a proposal regarding these State-level issues but instead, we sought comment on whether any of our proposals for the two-sided model in particular, or the Shared Savings Program in general, would trigger the application of any State insurance laws, the adequacy of those provisions that we have set forth, and the ways that we can work with ACOs and States to minimize the burden of any additional regulation.

We do not believe it would be appropriate to subject ACOs to the same standards as health plans as a way to

ensure that beneficiaries receiving care from an ACO do not have less access to care or receive care of lesser quality. ACOs that will be participating in the Shared Savings Program are very different from health plans. Further, these regulations, which are based on Federal law, would not preempt State insurance laws that govern providers within individual States, nor would they override State and local protocols concerning ambulance transportation. In addition, we are not adopting the comments related to the application of the malpractice laws, including the recommendation that ACOs be exempt from State malpractice laws.

At this time, we are not able to provide a list of States that currently recognize or authorize ACOs under their State laws, or have pending legislation to recognize ACOs. We believe it would be best for those interested in the Shared Savings Program to obtain such information directly from their individual State insurance agency.

Final Decision: We would emphasize that under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries, and that the agreement to share potential losses against the benchmark would be solely between the Medicare program and the ACO. We will further consider these issues in future rulemaking should we become aware of any unexpected program issues that render States responsible for bearing any costs resulting from the operation of this program.

H. Additional Program Requirements and Beneficiary Protections

1. Background

Section 1899 of the Act (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. Therefore, we discuss in this section certain requirements for ACOs that we believe will protect beneficiaries by ensuring patient engagement and transparency, including requirements related to beneficiary notification and outreach, marketing, and public reporting.

Section 1899 of the Act sets forth a number of requirements for ACOs. In addition, section 1899(a)(1)(A) of the Act authorizes the Secretary to specify additional criteria that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. In this section, we discuss 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.

Programs that include incentives to reduce costs for care may result in unintended consequences such as avoidance of at-risk patients, ''stinting'' on care, fraud and abuse, overutilization, deliberate delay in claims submission, and other such activities. We must ensure that beneficiaries continue to receive high quality and appropriate care, and that providers do not put beneficiaries or the Trust Fund at risk. In this section we also discuss our program integrity requirements, which we believe will help to deter inappropriate conduct by ACOs, while protecting the Trust Fund and the integrity of the Shared Savings Program and the Medicare program as a whole.

2. Beneficiary Protections

a. Beneficiary Notification

As we discussed in the proposed rule, the statute does not mandate that ACOs should provide information to beneficiaries about the Shared Savings Program. Such information could include whether the beneficiaries are receiving services from an ACO participant or ACO provider/supplier, or whether the beneficiaries' expenditure and quality data may be used to determine the ACO's eligibility to receive a shared savings payment. However, we believe the Shared Savings Program lays the foundation for a beneficiary-centered delivery system that should create a strong relationship between beneficiaries and care providers based, in large part, on patient engagement in the new care system. Such engagement would be more difficult if beneficiaries are not aware of the new delivery system available through ACOs, or the possibility of their being data used to assess the ACO's performance. In short, we believe transparency must be a central feature of the Shared Savings Program.

In the proposed rule, we stated that we intended to develop educational materials and other forms of outreach, to provide beneficiaries with timely, accurate, clear, and understandable information about the Shared Savings Program. Additionally, we indicated that we would update the annual Medicare & You Handbook to contain information about the Shared Savings Program and ACOs.

In the proposed rule, we proposed specifically to require ACO participants to post signs in their facilities indicating their ACO provider's/supplier's participation in the Shared Savings Program and to make available standardized written information developed by CMS to the Medicare FFS beneficiaries whom they serve. ACO participants would be required to provide standardized written notices of both their ACO provider's/supplier's participation in the Shared Savings Program and the potential for CMS to share beneficiary identifiable data with the ACO.

Likewise, we discussed whether beneficiaries should be made aware when an ACO participant does not renew its agreement at the end of the agreement period, or an ACO's participation agreement has been terminated. Thus, we proposed that ACOs be required to provide beneficiaries notice in a timely manner if the ACO participant or ACO provider/supplier will no longer be participating in the Shared Savings Program. We proposed the notice should include the effective date of the termination of the ACO agreement.

For a complete discussion of these notification proposals and rationale, please refer to the proposed rule published April 7, 2011 (76 FR 19567).

Comment: Many commenters supported our proposal to require ACO participants to notify FFS patients at the point of care that their ACO provider/supplier is participating in this Shared Savings Program. Some suggested CMS collaborate with stakeholders to educate beneficiaries about ACOs and the program and to seek stakeholder input on the materials CMS intends to provide, given the complexities of the program. Some suggested ensuring that language is culturally and linguistically appropriate and addresses low health literacy levels. Others suggested notices should include a detailed explanation of the expectations for patient engagement under the Medicare Shared Savings Program, and the ability of patients to receive care outside the ACO if they wish. Others suggested that ACOs be required to obtain the signature of the beneficiary in order to provide a mechanism for monitoring compliance with this requirement.

Commenters varied in their opinion of whether notification of the program should come from the ACO or CMS. One commenter suggested first contact should be from practitioners as trusted partners in the beneficiary's care, rather than from CMS. Other commenters suggested that CMS should ''bear the financial responsibility for such a

program'' and that ''since the Medicare program has created a strong relationship with its beneficiaries, it is more appropriate that the Medicare program take all responsibility for notifying beneficiaries of the benefits and opportunities of receiving care through an ACO.'' Some suggested that CMS send a letter to a participating PCP's active Medicare patients on an annual basis notifying them of the potential use of their data to assess ACO performance, and that all communications to beneficiaries should be written in ''plain English''.

Conversely, some commenters strongly objected to the proposed notification requirements for ACOs, suggesting that signs, even if developed by CMS, would not be able to convey the complexities of the program and would be ''confusing and annoying'' to beneficiaries as well as ''onerous and burdensome'' to ACOs. A health care public policy center criticized the sign proposal as ''costly, of unproven value, and duplicative given the requirement to provide written information, and therefore contributing to the problem of unnecessary administrative and financial burdens on ACOs.''

Response: We agree with those commenters who advocated that we retain a notification policy in this final rule. We believe that our proposal to inform beneficiaries at the point of care was tested and successfully employed in the PGP demonstration, and did not prove to be ''annoying'' or ''confusing'' to beneficiaries. Although we appreciate one commenter's concerns that the sign proposal might be costly, of unproven value, and duplicative, we believe that posting signs will serve the purpose of calling the attention of beneficiaries to the existence of the ACO and the choice of the ACO participant and its ACO providers/suppliers to participate in it, ultimately resulting in increased transparency and the opportunity for improving beneficiary engagement in this care delivery model. We believe that it is useful and important for every fee-for-service beneficiary to know they are receiving services from participants in such a program, even those beneficiaries whose data will not ultimately be used to assess the ACO's performance. This is because ACOs are intended to develop special methods for coordinating care and improving quality that should affect the care of every beneficiary and improve the engagement of the beneficiary as a consumer of health care, whether that beneficiary is ultimately ''assigned'' to the ACO or not. The presence of signs and written materials will provide a useful initial notification for every beneficiary and that could encourage beneficiaries to raise questions and engage in discussions with the physicians and other providers about the ACO and its potential effects on their care and to become a more active consumer and partner in the care delivered. Nor should posting signs be inappropriately burdensome, since CMS will develop appropriate language and there will be a limited number of locations in each ACO in which the signs will need to be posted. Finally, we believe that the notice should appropriately come from the ACO participant and its associated ACO providers/suppliers because this is the first and most immediate point of contact with the beneficiary. Therefore, we believe that it is appropriate to finalize the requirement that the ACO agree to post signs in the facilities of ACO participants indicating the ACO provider's/supplier's participation in the Shared Savings Program and make available standardized written notices to Medicare FFS beneficiaries whom they serve.

We agree with the recommendation from commenters suggesting we ensure the use of ''plain writing'', and we would note that President Obama signed the *Plain Writing Act of 2010* on October 13, 2010, which is intended to promote clear Government communication that the public can understand and use.'' We will incorporate the requirements of the Plain Writing Act in all CMS communications and standardized language regarding the Shared Savings Program. We will also clarify that beneficiary communications, such as notifications of provider participation in an ACO in the Shared Savings Program, must meet the applicable marketing guidelines described later in this section.

Final Decision: We are finalizing our proposal to require ACO participants to post signs in their facilities indicating their associated ACO provider's/supplier's participation in the Shared Savings Program and to make available standardized written notices developed by CMS to Medicare FFS beneficiaries whom they serve. All standardized written information provided by CMS will be in compliance with the Plain Writing Act of 2010. We are clarifying that the standardized written notices must be furnished in settings in which fee-for-service beneficiaries are receiving primary care services.

Additionally, as we noted in the proposed rule, under a retrospective assignment methodology it would not have been possible for ACOs to notify beneficiaries of the ACO's participation in advance of the period in which the beneficiary may seek services from an ACO participant or ACO provider/supplier. We believe the revised policy of preliminary prospective assignment with retrospective reconciliation that we are establishing in section II.E. of this final rule gives ACOs the information necessary to provide advance notice, if the ACO so chooses, to some beneficiaries who have previously received services from ACO providers/suppliers and who are likely to continue to do so. Specifically, we are revising our policy such that ACOs may choose to provide notification of their participation to the beneficiaries who appear on the preliminary prospective assignment list and quarterly assignment lists (described in section II.D. of this final rule).

Finally, to minimize beneficiary confusion and reduce burden on ACOs and its ACO providers/suppliers, we are modifying our rule such that in instances where either an ACO does not renew its agreement at the end of the agreement period, or an ACO's participation agreement is terminated, ACOs will not be required to provide beneficiaries notice that the ACO, its ACO participants and its ACO providers/suppliers will no longer be participating in the Shared Savings Program. Similarly, ACO participants and ACO providers/suppliers that terminate their participation in an ACO will not be required to provide such notice to beneficiaries. All beneficiary notification and signage are included in the definition of ''marketing materials and activities'' and must comply with applicable marketing requirements described later in this section.

b. ACO Marketing Guidelines

We realize that care coordination is an important component of the Shared Savings Program; however, the potential for shared savings may be an incentive for ACOs, ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO's activities to engage in marketing behavior that may confuse or mislead beneficiaries about the Shared Savings Program or their Medicare rights.

As an aspect of patient centeredness, we stated in the proposed rule we believe it is appropriate and consistent with the purpose and intent of the statute to limit and monitor the use of beneficiary communications specifically related to the ACO operations or functions as well as ACO marketing activities and materials to ensure that such communications and marketing by ACOs are used only for appropriate purposes, such as notification that a beneficiary's health care provider is

participating in the ACO, issuance of any CMS required notices, or notification of provider or ACO terminations. We therefore proposed a definition of ACO marketing materials and activities and proposed that CMS approve materials or activities, or any revisions to previously approved materials in advance of their use. We proposed that failure to comply with marketing requirements could result in a CAP or termination, at our discretion. For a complete discussion of these notification proposals and rationale, please refer to (76 FR 19642).

Comment: Several beneficiary advocacy organizations submitted comments strongly supporting our proposed marketing guidelines. They shared our concern that beneficiaries could be misled into thinking that an ACO is similar to a managed care organization and that they must receive services some or all services from the ACO participants and associated ACO providers/suppliers. These commenters also raised concerns that beneficiaries could be targeted by aggressive marketers seeking to take unfair advantage of them. Additionally, some commenters offered specific suggestions for strengthening our guidelines such as—

- Making approval of an ACO's application to the program dependent on approval of their marketing materials;
- Expanding the definition of marketing materials and activities to include marketing via social media.
- Providing beneficiary notification in ''plain'' English.

In contrast, providers and provider advocates questioned the necessity and feasibility of our proposed marketing guidelines. These commenters disagreed that there is any significant potential for beneficiaries to be misled and noted that to require approval of marketing materials in advance imposes a financial and operational burden on the ACO. Some commenters posited that ACOs should be allowed to communicate with beneficiaries as necessary without any prior approval because physicians have long-standing relationships with their patients, families and the communities they serve, and their honesty with their patients is critical to maintaining open, positive relationships. These commenters recommended reducing the burden imposed by our proposal by, for example:

- Placing a limitation on review and approval of materials to those used specifically to notify beneficiaries of a provider's participation in an ACO and to describe the Shared Savings Program in addition to the notification informing beneficiaries of their opportunity to decline data sharing.
- Providing templates or model language for ACOs to use.
- Implementing a ''file and use'' method similar to the one used in the MA program and requiring the ACO to certify compliance with marketing requirements;
- Permitting ACOs to use outreach materials if they have been approved by a Regional Health Improvement Collaborative (RHIC) or if they have been developed and issued jointly with an RHIC.

Response: The wide range of comments demonstrates the importance of this topic to stakeholders, and the importance of balancing beneficiary protection with the burden marketing requirements imposed on potential ACOs. We agree with commenters that our definition of marketing materials should be refined in order to offer additional beneficiary protections. We agree with commenters that social media can be used as a marketing tool and therefore will modify our definition of ''marketing materials and activities'' to include social media, such as Twitter or Facebook.

We are also sensitive to the operational burden imposed by our proposal that the ACO seek prior approval before the use of any marketing materials. We decline the commenter's suggestion to make an ACO's application approval dependent on approval of marketing materials because it would not address the use of new or revised marketing materials and activities after the approval of an ACO's application to participate in the Shared Savings Program. In light of the comments, this final rule provides that marketing materials and activities may be used or conducted 5 business days following their submission to CMS, provided that the ACO certifies compliance with applicable marketing requirements and CMS does not disapprove the marketing materials and activities. This final rule further provides that marketing materials and activities are deemed approved after expiration of the initial five day review period, but permits CMS to disapprove marketing materials and activities at any time, including after the expiration of the initial 5 day review period. The ACO, ACO participant, or ACO provider/supplier, as applicable, must discontinue use of any marketing materials or activities disapproved by CMS and may be sanctioned for using disapproved marketing materials and activities.

We disagree with the commenter who suggested that there is little potential for marketing materials and activities to mislead beneficiaries. To ensure the accuracy of marketing materials, this final rule imposes a requirement that marketing materials and activities must not be inaccurate or misleading. In addition, we will make template language available for certain marketing materials and require that such template language be used when available. We agree with commenters that it is desirable for marketing and notification materials to be provided in ''plain writing'' according to the definition of the term ''plain writing'' which means writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience. We note that the Plain Writing Act of 2010, signed by President Obama on October 13, 2010, applies only to Government communications. To the extent that CMS supplies templates or model language for ACOs to use in marketing materials, we will ensure it complies with the Plain Writing Act of 2010.

In response to commenters recommending limiting review of only certain marketing materials and activities, we clarify that our proposed definition of marketing materials and activities includes materials ''used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers *regarding the Shared Savings Program.*'' Additionally, our definition of marketing materials and activities excludes materials that do not include information about the ACO, its ACO participants or its ACO providers/suppliers.

Comment: Commenters recommended that CMS prohibit certain behaviors such as discriminatory marketing directed at certain types of beneficiaries or beneficiaries with certain health profiles, marketing that misleads or confuses beneficiaries about benefits and services, making claims that the ACO is recommended or endorsed by Medicare. Commenters recommended modifying the definition of ''marketing materials and activities'' to remove the exception for ''informational materials customized or limited to a subset of beneficiaries,'' stating it creates a significant loophole for ACOs to engage in discriminatory behaviors.

Response: We understand the commenters' concerns and agree that targeting certain types of beneficiaries including beneficiaries with certain health profiles or beneficiaries with certain racial or ethnic profiles or with language barriers could be used in some circumstances to mislead beneficiaries and should be prohibited as discriminatory marketing. However, we

also believe that some targeted materials are necessary for care coordination. For example, an ACO may send materials targeted to heart patients because they have a specialized heart facility that can coordinate the care of such individuals. Requiring such materials to be sent to all beneficiaries would be less effective and imposes an additional financial burden on the ACO. Thus, where targeted materials promote beneficiary access and care coordination, they likely do not constitute discriminatory marketing. Because we do not believe that all targeted materials are necessarily discriminatory, we are not revising the definition of ''marketing materials and activities'' as suggested by the commenters. We are instead modifying the marketing requirements to provide that marketing materials and activities must not be used in a discriminatory manner or for discriminatory purposes.

Final Decision: We are finalizing the definition of marketing materials and activities without substantive change at § 425.20 of this final rule. We note that the definition is revised to include language proposed in the preamble that was inadvertently omitted from the proposed regulation text. Accordingly, § 425.20 excludes from the definition of marketing materials or activities those materials and activities that do not constitute ''marketing'' under 45 CFR 164.501 and 164.508(a)(3)(i).

Further, this final rule allows ACOs to use marketing materials 5 days after filing them with CMS if the organization certifies that the marketing materials comply with all applicable marketing requirements. We have revised the regulation to specify that all marketing materials and activities must use template language when available, must comply with the prohibition set forth at § 425.304(a) regarding certain beneficiary inducements, must not be used in a discriminatory manner or for discriminatory purposes, and must not be inaccurate or misleading. Materials will be provided in ''plain'' language that is easily comprehensible, clear, concise, well organized, and complies with requirements of the Plain Writing Act of 2010.

Finally, if ACOs are found not in compliance with marketing guidelines, they will be subject to penalties as discussed later in this section of the final rule.

c. Public Reporting and Transparency

Increasingly, transparency of information in the health care sector is seen as a means to facilitate more informed patient choice, offer incentives, and feedback that help improve the quality and lower the cost of care, and improve oversight with respect to program integrity. While the Act did not include a specific requirement for public reporting and transparency related to the Shared Savings Program, improved transparency would support a number of program requirements. In particular, increased transparency would be consistent with and support the requirement under section 1899(b)(2)(A) of the Act for an ACO to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it.

Therefore, as stated in the proposed rule, we believe it is desirable and consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's operation and performance to be transparent to the public. We proposed that certain information regarding the operations of the ACO would be subject to public reporting to the extent administratively feasible and permitted by law. We proposed that each ACO must be responsible for making this information available to the public in a standardized format that we will make available through guidance. This requirement would be included in each ACO's agreement. For a more complete discussion of these proposals and rationale, please refer to (76 FR 19653).

Comments: Numerous commenters wrote in support of public reporting and transparency but varied in their recommendations about how the reporting should occur. A few commenters suggested expanding public reporting beyond what was proposed. Some commenters supported ACOs reporting the data rather than CMS. However, other commenters believed that the cost and administrative burden of asking ACOs to report measures seemed unnecessary and possibly less effective than making CMS responsible for public reporting. One commenter suggested CMS work with states to develop public reporting sites. One commenter stated that both CMS and the ACO should report the data. A few recommended that ACOs be allowed some flexibility in how the reporting occurs in order to best meet the needs of their patients. A few commenters suggested public reporting not occur until the second or third year to allow ACOs to develop the necessary infrastructure and expertise. We received few comments regarding whether additional information should be required to be publicly reported by ACOs with a two-sided model. A few commenters suggested that ACOs be allowed to review and verify CMS data before the information is released.

Response: We believe it is consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's operation and performance to be transparent to the public. 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 it. Reports on ACO quality and cost performance will 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 measure data would 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. We believe publicly reporting certain ACO quality data on the Physician Compare Web site is a good first step toward Shared Savings Program transparency, consistent with comments and other quality program efforts. The mechanism for public reporting of other quality measures, such as measures of patient experience and claims- and administrative-based measures, will be addressed in guidance.

Final Decision: We are finalizing our proposal for public reporting as outlined in § 425.308. Consistent with the proposed regulation text, the final public reporting provision requires ACOs to publicly report the identity of each member of the governing body, not just the ACO participants.

We expect that the reporting of quality performance standards will align with the proposed new public reporting requirements under the Physician Quality Reporting System (76 FR 42841). Specifically, because an ACO will be considered to be a group practice under the Physician Quality Reporting System GPRO under the Shared Savings Program, we intend to report ACO quality performance GPRO measures on Physician Compare along with the performance of all other PQRS group practices. However, we note that this modification is contingent upon the final policies regarding public reporting under the PQRS, which will be announced in the CY 2012 Physician Fee Schedule final rule that will be issued later this year. We will issue guidance to provide ACOs with guidelines regarding public reporting of the quality performance scores.

3. Program Monitoring

a. General Methods Used To Monitor ACOs

In implementing other Medicare programs, including MA and the Medicare Prescription Drug programs,

we have gained extensive experience in monitoring organizational, provider, and supplier behavior with respect to compliance with the Medicare program and program integrity requirements, quality measurement, avoidance of particular types of beneficiaries, overutilization, and claims submissions. General monitoring methods can be used, for example, to assess whether the ACO provider/suppliers have been stinting on care provided to beneficiaries assigned to the ACO in an effort to artificially create savings to obtain a shared savings payment, or over utilizing items and services furnished to beneficiaries who are not assigned to the ACO in order to make up revenues it may no longer be receiving due to other efficiencies or to assess if an ACO is steering beneficiaries through selective billing for the purpose of affecting shared savings and losses. A number of factors may trigger our heightened oversight of ACOs by us, including conduct that may form the basis for terminating the ACO agreement described in this section II.H.5 of this final rule. Given the goals of the Shared Savings Program, we anticipate particularly close examination of ACOs that incur large losses.

In the proposed rule, we proposed to employ many of the methods we have developed for purposes of the MA and Medicare prescription drug programs to monitor and assess ACOs, ACO participants, and ACO providers/suppliers for noncompliance with statutory and regulatory eligibility and other program requirements. We proposed that the methods we could use to monitor ACO performance may include, but are not limited to the following:

- Analysis of specific financial and quality data as well as aggregated annual and quarterly reports.
- Site visits.
- Collection, assessment and follow up investigation of beneficiary and provider complaints.
- Audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits).

If based upon the results of our monitoring activities we conclude that the ACO may be subject to termination, we proposed to use our discretion to take any or all of the following actions prior to termination of the ACO from the Shared Savings Program:

- Provide a warning notice to the ACO describing the issue of concern.
- Request a CAP from the ACO.
- Place the ACO on a special monitoring plan.

We sought comment on additional actions or sanctions that may be appropriate prior to termination.

Comment: Some commenters agreed that a number of beneficiary protection policies within the ACO program, including rules around contacting the beneficiaries directly, monitoring avoidance of at-risk beneficiaries, monitoring beneficiary and provider complaints, record retention, termination, payment structure within the ACO, and monitoring quality metrics were needed to help avert any unintended consequences to beneficiaries.

Some commenters suggested additional protections were necessary, stating that our proposed monitoring methods lacked appropriate safeguards and operational details necessary to create a comprehensive program that is quality driven. Specifically, commenters suggested that the ACO should have a provider network that is inclusive of all medically necessary services, that ACOs should be held to the same standards required for MA plans, or that ACOs be required to implement a comprehensive independent monitoring program for monitoring ACO performance that includes collecting data on race and ethnicity, validating beneficiary satisfaction surveys, and providing oversight for financial solvency in order to ensure consumer protections and market stability.

Other commenters suggested that CMS implement an evaluation or monitoring program to allow lessons learned from this program to be integrated in the larger Medicare program and to determine the following: Whether an ACO is achieving desired goals, such as less fragmented care and improvement of quality of care beyond the set of identified performance measures; whether or not elements of the ACO structure are contributing to any identified improvements or whether they are having a negative effect; whether there are positive characteristics of certain ACOs that can be transferred to other ACOs; and whether ACOs work better in certain environments (rural vs. urban) or with certain populations. Finally, some commenters suggested that CMS should have just cause to audit an ACO or its participants because audits are costly and burdensome to Medicare providers. They suggested that CMS narrow the types of organizations to which it applies this open-ended audit policy or reduce monitoring requirements after an ACO has successfully delivered a minimum of 5 percent savings for 3 years in a row.

Response: We believe that the beneficiary and program monitoring and protections we are finalizing contain appropriate safeguards and are necessary to ensure that unintended consequences are minimized. We reiterate that the Shared Savings Program is built on the FFS system, and beneficiaries retain all rights and benefits under traditional FFS Medicare. Therefore, we do not believe it is necessary to impose the same protections or network adequacy requirements as are present in the MA program because the Shared Savings Program does not lock-in beneficiaries or restrict beneficiary access to services or their choice of providers. However, we have and will use our experience with monitoring MA plans to inform our monitoring of ACOs.

In our monitoring, we intend to rely primarily on claims-based measures and other information provided by beneficiaries and providers. We will conduct a sufficient number of audits necessary to assess ACOs performance. We disagree with the comments suggesting that we should narrow the number or type of organizations that are subject to audits or that audits should be conducted only if there is a suspicion of wrong doing of some other ''good cause'' to audit. To protect the program, we need the flexibility to audit and monitor compliance under a variety of circumstances. This is particularly critical for the Shared Savings Program, not only because it is a new program, but also because it includes the waiver of certain fraud and abuse authorities. However, as a practical matter, we may choose to target our resources to audit or monitor certain organizations or compliance with certain program requirements.

We agree with commenters that evaluation of the Shared Savings Program and ACOs can help us determine the impact and effectiveness of the program. We intend to improve the Shared Savings Program over time by integrating lessons learned by modifying program requirements as necessary to reflect lessons that demonstrated positive and effective characteristics of ACOs, or to mitigate any negative results. We may also use lessons learned to improve upon existing Medicare programs.

Final Decision: We appreciate both the support for our monitoring proposals by providers and the beneficiary advocate community, as well as the concerns expressed regarding the need for increased monitoring and concerns regarding burden on providers and ACOs. We believe our proposals balance these

concerns. Therefore, we will finalize without substantive change the proposal to use the many methods at our disposal to monitor ACO performance and ensure program integrity, including but not limited to, undertaking an audit if we determine it is necessary.

b. Monitoring Avoidance of At-Risk Beneficiaries

(1) Definition of At-Risk Beneficiaries

Section 1899(d)(3) of the Act authorizes the Secretary to ''impose an appropriate sanction'' on an ACO, including ''termination from the program,'' if the Secretary determines an ACO ''has taken steps to avoid patients at-risk in order to reduce the likelihood of increasing costs to the ACO.'' While the statute does not define what constitutes ''patients at-risk,'' we proposed a definition which is detailed in the proposed rule at (76 FR 19625). We sought comment on this definition of ''at-risk beneficiary'' and whether other beneficiary characteristics should be considered in determining whether a beneficiary is ''at-risk.''

Comment: Several commenters expressed concern that our definition of at-risk beneficiaries did not include certain high-risk diseases and conditions for which patients may need specialized care or follow-up during recovery. They made many suggestions for additional conditions or diagnoses that would cause a beneficiary to be considered at-risk such as—

- Persons with disabilities;
- Beneficiaries with limited proficiency in English or low economic status;
- Non-compliant patients;
- Patients who choose to have elective surgeries;
- Patients with recent diagnoses or conditions that are expected to result in increased cost, such as amputation, major multiple trauma, fracture of femur, various neurological disorders (such as stroke, spinal cord injury, brain injury, multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease), burns, bilateral knee and hip joint replacements, specific types of rheumatoid and osteoarthritis, transplant patients and beneficiaries with end-stage renal disease, persons diagnosed with diabetes or pre-diabetes, cancer patients and survivors;
- Patients with mental health or substance use disorders (MH/SUD); or
- Patients seen in an emergency room 3 times within 12 months.

Response: We believe that our proposed definition is general enough to include most of the specific suggestions made by commenters. For example, the suggestion was made to include beneficiaries who have brain injuries or other chronic conditions. We believe beneficiaries who have brain injury or other chronic conditions suggested by commenters are included in our proposed definition which we proposed in preamble would include beneficiaries who have one or more chronic conditions. We also believe that many beneficiaries with low socioeconomic status are included in our definition which includes dually eligible beneficiaries. We disagree that beneficiaries with limited proficiency in English should be included in the definition of at-risk beneficiaries. We do not believe that limited English proficiency puts patients at risk for significant increases in health care costs. However, we note, that this final rule prohibits ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities from engaging in discriminatory marketing directed at certain types of beneficiaries, includes those with language barriers. We believe that patients seen in an emergency room to three times in a 12 month period are included in the proposed definition of at-risk which specifically mentions emergency room use. However, we agree with commenters that our proposed definition should be expanded to include patients who are entitled to Medicare because of disability and those who are diagnosed with mental health or substance use disorders. Such conditions could also be very high-cost conditions and thus make these beneficiaries targets for avoidance. We also agree that as we learn more about the ACOs and the Shared Savings Program, other types of beneficiaries may be considered at-risk for avoidance

Final Decision: Given our reasoning described previously, we are finalizing the definition of at-risk beneficiary as proposed in § 425.20, with the addition of patients who are entitled to Medicaid because of disability and who are diagnosed with a mental health or substance abuse disorder.

(2) Penalty for Avoidance of At-Risk Beneficiaries

To identify ACOs that could be avoiding at-risk beneficiaries, we proposed to use a variety of methods that would begin with an analysis of claims and examination of other beneficiary-level documentation to identify trends and patterns suggestive of avoidance of at-risk beneficiaries. The results of these analyses could lead to further investigation and follow-up with beneficiaries or the ACO (including ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO's activities) in order to determine whether avoidance of at-risk beneficiaries has occurred. For example, as a part of our monitoring for avoidance of at risk beneficiaries, we would be interested in assessing the changes in risk adjustment of the assigned population over time. Changes in risk adjustment of the beneficiaries assigned in the prior year who are not assigned in the current performance year could help determine whether there is a pattern of avoidance. In cases where it appears the ACO has developed a pattern of avoidance, we stated we may determine an audit is necessary. If as a result of our analysis we conclude that an ACO has been avoiding at-risk beneficiaries during a performance year, we proposed to notify the ACO of our determination and to require the ACO to submit a CAP for our approval as discussed in later in this section II.H.5 of this final rule. We proposed that the CAP must address actions the ACO would take to ensure that the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities cease avoidance of at-risk beneficiaries and that the CAP must be implemented as approved. In addition, we proposed that the ACO would be re-evaluated both during and at the end of the CAP. If we determine that the ACO has continued to avoid at-risk beneficiaries, the ACO would be terminated from the Shared Savings Program. We also proposed that an ACO operating under a CAP because it has avoided at-risk beneficiaries would not receive shared savings payments while under a CAP regardless of the performance period in question, and would not be eligible to earn any shared savings for the period during which it is under this CAP.

We solicited comments on whether lesser sanctions would be appropriate when an ACO avoids at-risk beneficiaries.

Comment: Commenters shared CMS' concern that ACOs may seek to avoid at-risk beneficiaries. While the commenters did not directly address our proposed methods for monitoring, they did suggest that CMS implement a robust monitoring strategy to ensure beneficiary protections such as: Requiring ACOs to have an effective grievance process in place to ensure beneficiaries have recourse against unfair practices; requiring ACOs to provide access to specialists trained in

the care of complex, high-need patient populations (for example oncology patients or patients needing palliative or hospice care) across diagnostic categories and that the penetration of palliative care and hospice care among high-need high-cost beneficiaries be assessed; requiring ACOs to monitor primary care physician's referral patterns to ensure that medically necessary services are not denied to Medicare patients with cancer; use of individualized care plans for patients at-risk and other potentially critical conditions, and strict enforcement of penalties for avoiding beneficiaries.

A few commenters expressed concerns that CMS' proposal was not robust enough. These commenters stated they believe that CMS would only enforce penalties for avoiding patients at-risk in extreme circumstances and urged CMS to strictly enforce penalties. A few commenters suggested lesser sanctions, including the cessation of or reduction in the assignment of new beneficiaries, a reduction in the amount of shared savings payments, or a fine for each instance of avoiding an at-risk beneficiary.

Response: We believe that the proposed policy is necessary for beneficiary and program protections and is in accordance with section 1899(d)(3) of the Act. We do not agree that we should use the lesser sanctions suggested by the commenters for avoidance of at-risk beneficiaries because of the serious implications that avoidance of high risk patients has on Medicare beneficiaries. Also, this is a new program and we do not have any experience to determine the true severity of this issue. However, we may consider lesser sanctions as we gain experience. It is our intention to create policies that ensure beneficiary and program protections while minimizing the burden on ACOs. Since Medicare FFS beneficiaries have many mechanisms at their disposal to lodge their grievances against practitioners involved in their care (including 1–800 Medicare, the Medicare ombudsman's office, quality improvement organizations and others), we do not believe an additional grievance mechanism needs to be developed that is specific to ACOs. Instead, we will monitor complaints by beneficiaries assigned to ACOs that come in through these established mechanisms. We believe the CAP process described previously provides ACOs the opportunity to explain and correct any deficiencies to potentially avoid termination or other penalties. Therefore, we are finalizing our proposal to place ACOs under a CAP to correct the deficiency before termination of its participation agreement and to require the ACO to forfeit any shared savings it was eligible for while under the CAP. However, in response to comments, we will modify our proposal to retain the discretion to impose immediate termination in appropriate cases.

Final Decision: We are finalizing our proposal to use various methods at our disposal, as discussed previously in this section to monitor ACOs for avoidance of at-risk beneficiaries, and the actions we will take if we conclude an ACO has been avoiding at-risk beneficiaries (under § 425.316). In response to commenter concerns, we are retaining in this final rule the right to terminate immediately in appropriate cases.

c. Compliance With Quality Performance Standards

Section 1899(d)(4) of the Act authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. In the proposed rule, we made proposals related to termination of an ACO for failure to meet the established quality performance standards. For a complete discussion and description of our proposals, please refer to (76 FR 19625).

Comments: A few commenters believed that our proposal for monitoring compliance with quality performance standards were limited and insufficient. Commenters suggested that the language be revised to remove the warning for the first incident and to add language that the ACO will be evaluated during the subsequent 3 to 6 months depending on the number of affected beneficiaries and the seriousness of the problem, and if the ACO is still out of compliance, CMS may terminate the ACO or take other actions such as a reduction in shared savings payments. Additionally, commenters stated that CMS should differentiate between the failure to meet quality performance standards because of lack of data infrastructure rather than the failure to satisfy quality performance standards due to provisions of poor quality care. It was suggested that ACOs that furnish poor quality care should be subject to closer monitoring than ACOs that fail because of faulty data processes.

Response: We have considered the comments and agree that we should have flexible methods for enforcing compliance with the quality performance standards. We proposed in § 425.216 that the issuance of a warning letter followed by re-evaluation in 1 year applied *in addition to* the actions prior to termination set forth at proposed § 425.218. Thus, depending on the nature and severity of the noncompliance, we may forgo the issuance of a warning letter and instead place the ACO on a special monitoring plan or immediately impose a CAP and additional monitoring. At this time, we do not believe it necessary to create penalties or procedures in addition to those we proposed, although we have modified the regulation to permit immediate termination when warranted. We will consider appropriate additional penalties in the future as necessary.

Comment: A commenter suggested that when an ACO makes a written request for payment of shared savings (or acknowledges shared losses), it should describe how it was able to ensure that quality was not negatively impacted as a result of the changes it made to generate savings.

Response: Because an ACO cannot share in savings without satisfying the quality standards, we do not believe it is necessary to require an ACO to describe how it ensured that quality did not suffer as a result of its activities. With respect to ACOs that incur losses, we will be monitoring their quality performance and will take appropriate action in response to such monitoring. In light of the eligibility and program requirements, monitoring procedures, and sanctions provisions, we do not believe it is necessary to require ACOs, including those that incur losses, to submit a written description of how they ensured that quality was not negatively affected by the ACO's activities. The policy regarding a written request for shared savings has been modified as described later in this section.

Final Decision: We are finalizing our rule as proposed regarding termination for poor quality performance under § 425.316(c), except that this final rule permits for immediate termination or a CAP in addition to a warning letter for ACOs who are underperforming on quality performance standards.

4. Program Integrity Requirements

Section 1899(a)(1)(A) of the Act authorizes the Secretary to specify criteria that groups of providers of services and suppliers must meet in order to work together to manage and coordinate care for Medicare FFS beneficiaries through an ACO. Using this authority, we proposed several program integrity criteria to protect the Shared Savings Program from fraud and abuse and to ensure that the Shared Savings Program does not become a vehicle for, or increase the potential for, fraud and abuse in other parts of the

Medicare program or in other Federal health care programs.

Comment: Commenters generally agreed with the need for the proposed program integrity requirements. A few commenters expressed concern that although the ACO participants and ACO providers/suppliers undergo stringent screening to participate in Medicare, the ACO entity itself is not required to enroll in Medicare, which may make this program vulnerable to fraud, waste, and abuse. Several commenters suggested that our proposed program integrity requirements impose operational and administrative burdens on ACOs which would increase costs and distract organizations from focusing on improving care coordination and quality of care. Other commenters suggested strengthening our proposed requirements.

Response: The goal of our program integrity proposals are to protect the rights of beneficiaries and minimize the risk of fraud and abuse in the Shared Savings Program. We are seeking to strike the right balance between helping providers provide high quality coordinated and efficient care to Medicare beneficiaries, while also protecting the Medicare Trust Funds. Striking this balance requires us to ensure that the ACO implements certain compliance requirements. As described later in this final rule, we are adopting our program integrity proposals with clarification in this final rule.

Comment: A commenter expressed concern that because of financial pressures to reduce utilization and costs, practitioners will be exposed to an increased likelihood of malpractice suits. The commenter suggested that CMS create a specialty health court to handle suits against ACOs and their providers by ACO patients.

Response: We do not have the statutory authority to create such a system. We expect ACO providers/suppliers to provide high quality, coordinated care, and are adopting a number of monitoring strategies to ensure that they are meeting these requirements. As a result, it is not clear that malpractice litigation will increase, and indeed may decrease if beneficiary outcomes improve as a result of the activities of the ACO.

a. Compliance Plans

We proposed that an ACO have a compliance plan. We recognize that the specific design and structure of an effective compliance plan may vary depending on the size and business structure of the ACO. However, we proposed requiring that the ACO demonstrate that it has a compliance plan that includes at least the following elements: A designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body; mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance; a method for employees or contractors of the ACO, the ACO participants, or the ACO providers/suppliers to report suspected problems related to the ACO; compliance training for the ACO, the ACO participants, the ACO providers/suppliers; and a requirement for the ACO, its ACO participants, and other individuals or entities performing functions or services related to ACO activities to report suspected violations of law to an appropriate law enforcement agency. We also noted that an ACO may want to coordinate its compliance efforts with the compliance functions of its ACO providers/suppliers.

Comment: Commenters generally agreed with the proposed compliance plan requirement. However, a few commenters pointed out that they believe a compliance plan does not stop fraud, waste, and abuse. These commenters believe that the program requirements should be strengthened. Some commenters recommended that CMS establish compliance plan requirements and intermediate sanctions for the Shared Saving Program, similar to those used for Medicare Advantage programs or that CMS explain why it does not believe that an ACO should adhere to the same or similar requirements that MA organization must meet.

Response: We agree that compliance plans on their own do not stop fraud and abuse; however, compliance programs increase the likelihood of identifying and preventing unlawful and unethical conduct; provide a centralized source for distributing information on health care statutes, regulations, and other program directives related to fraud and abuse; and create an environment that encourages employees and others to anonymously report potential problems, among other benefits. We believe the compliance plan helps guide the organization in the right direction and is necessary to ensure the ACO is taking action regarding suspected fraud and abuse. Therefore, we are finalizing our proposal on compliance plans to require a method for employees or contractors of the ACO, the ACO participants, or the ACO providers/suppliers to anonymously report suspected problems related to the ACO and to require that ACOs report suspected fraud and abuse to an appropriate law enforcement agency. In addition to finalizing the compliance plan requirements, this final rule strengthens other program requirements and remedies (for example, we may impose immediate termination in appropriate circumstances) to minimize the potential for fraud and abuse.

Comment: One commenter suggested that CMS consider limiting the compliance training to the compliance officer to reduce some of the burden on ACOs.

Response: We believe that requiring compliance training for the ACO and all of its ACO participants and ACO providers/suppliers help to ensure that every ACO participant, ACO providers/suppliers, and contractor understands their legal obligations with respect to the ACO's operations and performance, as well as the requirements of the compliance program and the manner in which their ACO is implementing such requirements. Without compliance training, ACO participants, ACO providers/suppliers, and contractors may not be aware of potential compliance risks and how to report compliance concerns. We do not believe that only training the compliance officer is sufficient to ensure that the entire ACO is aware of compliance risks.

Comment: A few commenters disagreed with our proposal that the compliance officer is not permitted to also be legal counsel to the organization. These commenters suggested if CMS will not allow an attorney to be both legal counsel and compliance officer, it would be important to have a clear statement from CMS that an attorney may not serve as the compliance officer.

Response: We believe it is important that the authorized, designated compliance officer not also be the legal counsel to the organization. However, many compliance officers are trained as attorneys, and we did not mean to suggest that an attorney would not be able to serve as a compliance officer. We clarify that the legal counsel to the ACO and the compliance officer must be different individuals, in order to ensure independent and objective legal reviews and financial analyses of the organization's compliance efforts and activities by the compliance officer. We are also clarifying that for existing organizations, ACOs can use their current compliance officer, who must report directly to the ACO's governing body, provided that the compliance officer is not legal counsel to the existing organization. We believe this decision allows the ACO to take full advantage of the compliance

requirements already in existence and reduces the burden on ACOs.

Comment: One commenter believed that attempting to meet legal requirements of two or more different entities in cases such as when providers may be participating in an ACO for some patients, but continue to function as an independent provider for others can create considerable complexity and confusion.

Response: In order to provide ACOs with the flexibility they need to define a compliance plan that meets the needs of the ACO, its ACO participants, its ACO providers/suppliers, and contractors, we decline to specify how various organizations should work together to develop their plan. We look forward to innovation from the industry in this area. We will monitor reports of any difficulty in this area and may address this issue further in future rulemaking.

Comment: A few commenters recommended that the requirement to report suspected violations of law to an appropriate law enforcement agency be removed because it deviates from accepted compliance practices. The commenters pointed out that the phrases ''suspected violations'' and ''suspected fraud, waste, and abuse'' are unclear and too general. Additionally, commenters are concerned that this reporting requirement suggests that there is no chance for the ACO to resolve the problem first, before reporting it.

Response: Health care providers have had compliance obligations for many years and have developed successful approaches to combating fraud and abuse in their organizations. The Office of the Inspector General has outlined industry best practices for compliance programs as well as a description of the risks of fraud and abuse that various providers may face. We suggest that providers without experience developing compliance programs review the various resources that are available from the OIG'S web site to help determine the risk of fraud and abuse in the ACO and when an activity may rise to the level of a violation that may need to be reported. The Office of the Inspector General has consolidated its compliance guidance at: *http://oig.hhs.gov/compliance/compliance-guidance/index.asp*. Resources are also available for ACOs and ACO participants to self disclose potential violations. For example, the Medicare self-referral disclosure protocol for potential violations of the physician self-referral statute is available at: *https://www.cms.gov/physicianselfreferral/65_self_referral_disclosure_protocol.asp* and the OIG's provider self-disclosure protocol is available at: *http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf.*

We believe ACOs should have a compliance program that allows for the prompt and thorough investigation of possible misconduct by ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities, corporate officers, managers, employees, and independent contractors, as well as, early detection and reporting of violations, thus minimizing the loss to the Federal government from false or improper claims and thereby reducing the ACO and ACO participants' and its ACO providers/suppliers' to applicable civil damages and penalties, criminal sanctions, or administrative remedies, such as program exclusion, as applicable. As such, ACOs should consider implementing a system for identifying and addressing possible violations when designing their compliance plan. We are modifying the final rule to provide that ''probable'' violations should be reported to law enforcement.

Final Decision: We are finalizing our proposed compliance plan requirements with minor modifications, as outlined in § 425.300. Like the proposal, the final rule allows an ACO to coordinate and streamline compliance efforts with those of its ACO participants and ACO providers/suppliers. We have added a provision requiring compliance plans to be updated periodically to reflect changes in law, including new regulations regarding mandatory compliance plan requirements of the Affordable Care Act. In addition, we provide that ''probable'' violations of law should be reported to law enforcement. Finally, we clarify that although both legal counsel to the ACO and the compliance officer may have a legal education, legal counsel to the ACO and the compliance officer must be different individuals. ACOs may use their current compliance officer, who must report directly to the ACO's governing body, provided that the compliance officer is not legal counsel to the existing organization and meets the requirements of § 425.300.

b. Compliance With Program Requirements

We proposed that, notwithstanding any relationships that the ACO may have with other entities regarding ACO related activities, the ACO maintains ultimate responsibility for compliance with all terms and conditions of its participation agreement with CMS. We proposed to require that all contracts or arrangements between or among the ACO, its ACO participants and ACO providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the ACO's obligations under its agreement with CMS, including the document retention and access requirements discussed in this section II.H.4.f of this final rule. Further, we proposed that an individual with the authority to legally bind the ACO (for example, the ACO's chief executive officer (CEO), chief financial officer (CFO)) must certify the accuracy, completeness, and truthfulness of information contained in its Shared Savings Program application, agreement with CMS, and submissions of quality data and other information. The certification must be made at the time the application, agreement, and information is submitted.

We proposed that, as a condition of receiving a shared savings payment, an individual with the authority to legally bind the ACO (for example the ACO's chief executive officer (CEO) or chief financial officer (CFO)), must make a written request to CMS for payment of the shared savings in a document that recertifies the ACO's compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted to CMS by the ACO, its ACO participants, or its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities to CMS, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of, a shared savings payment. To ensure the accuracy of information relied upon in calculating shared losses, we proposed to require submission of a similar recertification by an ACO that incurs losses under the two-sided model. We further proposed that, if any data or information on which we rely to determine shared savings or losses are generated by ACO participants or another entity, or a contractor, or subcontractor of the ACO, the ACO participants or the ACO provider/suppliers, must similarly certify the accuracy, completeness, and truthfulness of the data and provide the government with access to such data for audit, evaluation, and inspection.

Comment: A few commenters were concerned about the requirement that a single, authorized representative of the ACO must ''certify the accuracy, completeness and truthfulness of information contained in the Shared

Savings Program application.'' as well as quality data and other data, because the penalty for an individual's false certification, is not clear. The commenters were concerned that, given the amount of data being provided and the variety of individuals and entities other than the ACO that may generate the data (for example, ACO participants, ACO providers/suppliers, and contractors to such entities), it is possible that the ACO may unintentionally submit some incorrect information. The commenters recommended a ''to the best of my knowledge'' attestation or some other resolution that would apportion the responsibility to submit accurate information among the ACO, ACO participants, ACO providers/suppliers and their contractors.

Response: An individual or entity may be prosecuted under Federal law for the submission of false information, including a false certification, only if he or she knowingly submits false information (that is, with actual knowledge of its falsity or in reckless disregard or deliberate ignorance of the truth or falsity of the information). If the individual or entity later realizes that incorrect information has been submitted unintentionally, the individual or entity must timely submit corrected information. We expect that the submission and certification of forms, data, and other information will be completed by an appropriately authorized individual who knows or should know that the information submitted is true, accurate, and complete. Although we did expressly state in the preamble that the certification must be provided to the best of the certifying official's knowledge, information, and belief (76 FR 19544), we acknowledge that this language was not included in the text of the proposed regulation. As such, we wish to clarify that the certification language may include ''to the best of my knowledge or belief'' or similar language appearing in other Medicare certifications. We will provide the forms that require certification in guidance. We note that if it is discovered that the authorized designee knew or should have known that the information submitted was inaccurate, then he and/or the ACO, and/or the participants/providers/suppliers could be subject to liability for making false statements, termination, or other sanctions.

Comment: Some commenters thought that we proposed a cumbersome or burdensome process for requesting payment of shared savings and recertifying the accuracy of the information relied upon for calculating shared savings and losses.

Response: We agree a simpler process is warranted, although it is critical that ACOs certify the accuracy of information we rely upon in calculating shared savings and losses. We will require ACOs to certify after each performance period the accuracy of all information and data that we rely upon in determining eligibility for shared savings, the amount of any shared savings payments, and the amount of shared losses, if applicable. If the ACO or one of its ACO participants or ACO providers/suppliers has become aware that incorrect information was submitted during the performance year, corrected information must be submitted before the recertification.

Final Decision: We are finalizing, at § 425.302, our proposals with the clarification described previously and the modification that ACOs will be required to submit annual certifications by the timeframe CMS will establish through guidance.

c. Conflicts of Interest

We proposed that the ACO governing body have a conflicts of interest policy that applies to members of the governing body. For a full discussion of this proposal and the rationale for it, please refer to the proposed rule (76 FR 19643).

Comment: A commenter asked CMS to provide examples of conflicts of interest members of the governing body should disclose.

Response: The existence of a conflict of interest may vary depending on the composition and activities of an ACO, as well as other factors. In general, we believe that an ACO should adopt an appropriate conflict of interest policy consistent with relevant best practices in the industry and general principles of good corporate governance. An ACO should consider the variety of potential conflicts of interest that may exist among of members of the governing body, the term of applicable State and Federal laws, and other relevant concerns when adopting a policy that fits the scope of the ACO's operations.

As a starting point for organizations unfamiliar with conflict of interest policies, a sample conflict of interest policy for organizations exempt from Federal income tax is available from the Internal Revenue Service in the Instructions for Form 1023 Appendix A at *http://www.irs.gov/instructions/i1023/ar03.html.* ACOs should consider sample conflict of interest policies as a starting point only and should customize the policy for their operations.

Final Decision: We finalizing without change our proposal to require the ACO governing body have a conflict of interest proposal that applies to members of the governing body under § 425.106(d).

d. Screening of ACO Applicants

Although the Medicare program includes substantial screening procedures for enrolling providers and suppliers, ACOs may not be subject to those procedures if they are not providers that are eligible to enroll in Medicare. We proposed to screen ACOs during the Shared Savings Program application process with regard to their program integrity history, including any history of program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. We proposed that ACOs whose screening reveals a history of program integrity issues and/or affiliations with individuals or entities that have a history of program integrity issues may be subject to rejection of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks. We sought comment on the nature and extent of such screening and the screening results that would justify rejection of an application or increased scrutiny.

Comment: Several commenters supported the proposed screening process.

Response: We appreciate the commenters' support of the proposal. We believe it is important to set a level of screening that is appropriate to address the risk of fraud and abuse in the Shared Savings Program.

Comment: One commenter found our proposal confusing because it appeared to contain conflicting language about whether ACOs would be subject to screening. Other commenters were concerned that because an ACO does not go through the Medicare enrollment process, the potential for fraud and abuse would be increased. Commenters recommended that ACOs enroll in the Medicare program using the Provider Enrollment, Chain and Ownership System (PECOS). One commenter asked CMS to discuss the screening procedures for the Shared Saving Program and explain how the screening procedures will be any different for physician offices and hospitals than what were in place before the publication of the final rule with comment period entitled ''Medicare, Medicaid, and CHIP; Additional Screening Requirements, Applications Fees, Temporary Enrollment Moratoria,

Payment Suspensions, and Compliance Plans for Providers and Suppliers'' that appeared in the **Federal Register** on February 2, 2011 (76 FR 5862) (the ''provider screening rule'').

Response: Providers of services and suppliers that desire to participate in the Medicare program are subject to the screening procedures set forth in a provider screening rule. For example, an ACO that is a provider of services, such as a hospital employing ACO professionals, would be eligible to enroll in Medicare and would undergo the usual screens at enrollment. However, if the ACO entity is not a provider of services or a supplier that is eligible to enroll in Medicare, the ACO would not undergo the same screening procedures applicable to providers of services or suppliers, or be required to submit enrollment information through PECOS. For example, if some providers or suppliers that are not already integrated join together to form an ACO, they must create a new legal entity as described in section II.B.3 of this final rule. Such an ACO is not eligible to enroll in Medicare and would not undergo the usual screens.

Therefore, in addition to considering the program integrity history of ACOs and ACO participants that can enroll in Medicare, we proposed a separate screening process for ACOs that are not eligible to enroll in Medicare in order to ensure that the ACO undergoes appropriate screening prior to participating in the Shared Savings Program. Due to statutory limitations, we are unable to apply the provisions of the provider screening rule to ACOs that are not eligible to enroll in Medicare.

Comment: Commenters believed that the proposed screening requirements are too broad and should be narrowed based on the nature of the relationship between an ACO applicant and an entity with a history of program integrity issues. It was suggested that CMS consider parameters so that potential rejection or exclusion by CMS is not so broad as to prevent reasonable and appropriate participation by organizations that have only passing contact with potentially problematic providers.

Some commenters believed that a provider operating under a corporate integrity agreement is committed to correcting any error it may have made in the past and putting in place new procedures to prevent any future concerns and that these providers should not be excluded from participation in the Medicare Shared Savings Program.

A few commenters were concerned that increased attention to program integrity may also lead to increased reports of unfounded and inaccurate allegations being made by CMS and its contractors against Medicare providers; therefore, program integrity allegations should not be held against aspiring or approved ACOs until the claims have been fully adjudicated.

Response: We believe that the results of the screening will need to be considered in light of the relevant facts and circumstances. Therefore, we decline to draw a bright line regarding when an entity's history of program integrity issues justify denial of a Shared Savings Program participation agreement. We would likely consider the nature of the applicant's program integrity issues (including the program integrity history of affiliated individual and entities), the available evidence, the entity's diligence in identifying and correcting the problem, and other factors. We intend to ensure that ACOs, ACO participants, and ACO providers/suppliers would not pose a risk of fraud or abuse within the Shared Savings Program while recognizing that some program integrity allegations may not have been fully adjudicated.

Comment: Some commenters had concerns that the proposed rule is a violation of the Administrative Procedures Act and the commitment to government transparency by the current Administration. These commenters recommended that CMS solicit public comments through the proposed rulemaking process prior to establishing a screening process for ACOs.

Response: We included a proposal to screen ACOs that are not eligible to enroll in Medicare and solicited comments on our proposal in the proposed rule. We have considered public comments on the proposal to make our final decision, in accordance with the notice and comment rulemaking provisions of the Administrative Procedures Act.

Final Decision: We finalize our proposed screening requirements without change. ACOs and ACO participants that are providers of services or suppliers who are eligible to enroll in Medicare will be subject to screening in accordance with applicable regulations, and their program integrity experience will be considered when reviewing the ACO's application to participate in the Shared Savings Program. For ACOs that are not eligible to enroll in Medicare, we will consider the ACO's program integrity history, including any history of program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues, as a part of our application process. We clarify that our screening process will be based upon the information submitted with the ACO's application as further described in section II.B. of this final rule. An ACO whose screening reveals a history of program integrity issues and/or affiliations with individuals or entities (including ACO participants and ACO providers/suppliers) that have a history of program integrity issues may be subject to rejection of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

e. Prohibition on Certain Required Referrals and Cost Shifting

In the proposed rule, we stated that we are concerned that ACOs, their ACO participants, or their ACO providers/suppliers may offer or be offered inducements to over utilize services or to otherwise increase costs for Medicare or other Federal health care programs with respect to the care of individuals who are not assigned to the ACO. We noted that this risk might be heightened if the final rule provides for prospective assignment of beneficiaries. In other words, we are concerned that ACOs, ACO participants, or ACO providers/suppliers might shift Medicare or Federal health care program costs for other beneficiaries not assigned to the ACO.

To address the risk of this inappropriate cost shifting, we stated that we were considering prohibiting ACOs, and ACO participants from conditioning participation in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, and its ACO providers/suppliers know or should know is being provided to beneficiaries who are not assigned to the ACO.

Comment: One commenter stated that there is no perceived risk of abuse or inappropriate cost shifting with prospective assignment and that the Medicare program already causes cost shifting so the concern about new cost shifting is misplaced. A commenter expressed concerns that the rule did not address potential drug cost shifting from Part B to Part D and suggested that CMS develop mechanisms in the event that an ACO shifts drug utilization by not allowing patients to receive their appropriate medication and puts patients at-risk. Another commenter was concerned that ACOs, ACO participants, and ACO providers/suppliers who also participate in the 340B program (a program that allows physicians to purchase outpatient drugs at a discount rate and administer those drugs to their

patients) may purchase and administer drugs for patients of other ACO participants and providers/suppliers. This commenter suggested that CMS work with HRSA to gain a better understanding of the 340B program and establish protections against fraud, waste, and abuse.

Response: This final rule adopts a preliminary prospective assignment methodology with final retrospective reconciliation, as fully described in section II.E. of this final rule. We disagree with the commenter that there is no potential for inappropriate cost shifting in a prospective assignment model. We remain concerned that some ACOs, ACO participants, and ACO providers/suppliers, while working together to decrease costs for beneficiaries preliminarily assigned to the ACO, might inappropriately offer or be offered inducements to over utilize services or otherwise increase Federal health care program expenditures for beneficiaries not assigned to the ACO. To this end, our final regulations prohibit an ACO from conditioning participation in the ACO on referrals of non-ACO business.

We recognize the importance of appropriate beneficiary drug utilization and the concerns of the commenter regarding potential cost shifting of drug costs from Part B to Part D. As part of our ACO monitoring activities, described previously in this section, we intend to monitor the available claims data to detect patterns of cost shifting in the Federal health care programs by ACOs, including patterns of shifting drug costs. The ACO is not itself a 340B eligible entity. Health care providers in an ACO that participates in the 340B program must continue to meet all the requirements of the 340B statute, including ensuring they are not diverting drugs to non-patients or receiving duplicate discounts. A 340B provider is prohibited from purchasing or transferring drugs to non-340B entities and patients of non-340B providers, including those which are a part of an ACO. We will consult with HRSA regarding the risk of fraud and abuse in the 340B program to determine if there are additional monitoring needs for ACOs participating in the 340B program.

We intend to review specific circumstances of inappropriate cost shifting to determine if corrective action or other sanctions, is necessary

Comment: A commenter expressed the need for clarification as to how our proposal will successfully mitigate cost shifting in the Medicare program to patients outside of ACOs. Commenters also expressed concerns that ACOs will shift costs to other health plan types in the private sector by stinting on care. One commenter noted that the private market could also face cost shifting as an attempt to recover losses incurred by ACO participants and ACO providers/suppliers under the proposed two-sided model.

Another commenter recommended that CMS: (1) Require all participating ACOs to have a mechanism for assessing performance on private sector per capita costs by the second year of the program; gather data regarding current market shares, market entries and exits, and pricing trends for the ACOs; (2) set expectations for resource stewardship and waste reduction, including public reporting of quality and cost metrics (for example, cost to charge ratios, professional fee billing rates, prices for episodes for public and private payers, total costs for beneficiaries assigned to the ACO for public and private payers, etc.); (3) specify a standardized set of measures for costs, with input from consumers, purchasers, and other stakeholders; (4) hold ACOs in the Shared Savings Program to a maximum threshold of price increase with their commercial market clients; and (5) require ACOs take part in all-payer claims databases. Finally, one commenter suggested that we coordinate with the FTC and DOJ to thwart anti-competitive behavior.

Response: We expect ACOs to manage resources of all payers carefully and respectfully and ensure continual waste reduction so that every step in care adds value to the beneficiary. However, we share the commenters' concern that there is potential for ACOs to shift costs to other health plan types in the private sector and to engage in anti-competitive behavior.

In section II.C. of this final rule we discuss our concerns about issues related to market power and the interaction of the Shared Savings Program with the antitrust laws. As part of our ACO monitoring activities, described previously in this section, we intend to monitor the available data to detect patterns of cost shifting by ACOs. However, we recognize that we do not hold the private sector claims data that would be necessary for a complete analysis. We will work in consultation with the Federal Trade Commission (FTC), the Department of Justice (DOJ) Antitrust Division, and the HHS OIG, as appropriate, if patterns of inappropriate cost shifting in the Shared Savings Program are reported to identify any needed responses on our part or the part of other Federal agencies.

We are unable to implement the five suggestions raised in the last paragraph of the comment summary because they are outside the scope of the statutory authority of the Shared Savings Program, were not included in the proposed rule for public comment, or require analysis of data that is not currently available to CMS.

However, please see section II.F. of this final rule for a full discussion of our quality measurement requirements, which have undergone notice and comment rulemaking to obtain public input and which may be refined in the future to include additional measures regarding cost and efficiency. This section also describes the information we plan to report publicly regarding shared savings or losses data for each ACO.

Comment: Commenters stated that CMS should establish a strict prohibition against any behavior that seeks to limit the ability of an ACO provider/supplier to referral beneficiaries to professionals who are not participating in the ACO. One commenter expressed concern with his experience that network providers use coercive methods to keep patients ''within network,'' or to ensure that the patients receive care from a particular provider or supplier, which may be owned by the physician or his or her employer. The commenter asserted that such methods may include a physician's refusal to order services or to continue to serve as the patient's treating physician. The commenter asked CMS to make sure such methods will not be permitted and to describe how patient freedom of choice will be enforced. Another commenter asked whether an ACO would be deemed to be diminishing or restricting the rights of beneficiaries assigned to it if it—(1) required its ACO providers, consistent with its care coordination and management efforts under the Shared Savings Program, to refer the ACO's assigned beneficiaries to ACO participants and ACO providers/suppliers to the extent services are available from those parties, unless the beneficiary specifically requests referral to another provider or supplier; and (2) provided written notice of the foregoing to its assigned beneficiaries, to include notice that the beneficiary retains freedom of choice to select a provider of services or supplier, and that such freedom of choice, as communicated to the ACO provider making any such referral, will be respected.

Response: The Shared Savings Program maintains the beneficiary's freedom under Medicare FFS program to choose any participating Medicare provider for care. We anticipate that beneficiaries will prefer receiving care

from the ACO, the ACO participants, and the ACO providers/suppliers because the care will be patient-centered and coordinated among providers. We expect that the ACO, its ACO participants, and its ACO providers/suppliers will discuss the need for services with the beneficiary using shared decision-making. However, such discussions should not serve as roadblocks to beneficiaries who seek to obtain high quality care from the providers or suppliers of their choice. We understand commenters' concerns regarding behavior that seeks to limit or restrict referrals to professionals who are participating in the same ACO, but we also are concerned that a strict prohibition as advocated by some commenters would disrupt arrangements that are permitted under the physician self-referral law (see § 411.354(d)(4)), thereby requiring the restructuring of many legitimate arrangements. Therefore, we are modifying our final rule to prohibit limiting or restricting referrals of beneficiaries to ACO participants or ACO providers/suppliers within the same ACO, or to any other provider or supplier except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the judgment of the referring party. For example, an employer or contracting entity, such as a hospital, may require its employees and contractors to refer to the employer or contracting entity (for example, to the hospital's laboratory or imaging center), provided that the referring party is free to honor patient choice, insurer requirements, and medical best interests of the patients. As part of our ACO monitoring activities, described in this section, we intend to monitor the actions of ACOs, including the results of beneficiary experience of care surveys, to determine whether an ACO, its ACO participants, or its ACO providers/suppliers are interfering with the beneficiary's freedom of choice by improperly limiting or restricting referrals and care to ACO participants or ACO providers/suppliers in the same ACO.

Comment: One commenter advocated that we interpret the fraud and abuse laws liberally for purposes of the Shared Savings Program because Congress has recognized that such laws were written and interpreted for a health care delivery system designed for different payment incentives and not with ACOs in mind. However, other commenters stated that that the remedies do not provide enough protection from the compliance risks associated with the physician self-referral law, anti-kickback statute, antitrust laws, and other regulations. One commenter was troubled by the proposal to waive the physician self-referral law, anti-kickback statute, and civil monetary penalties law because ACOs create incentives similar to those that have historically concerned CMS and these laws are paramount to protecting Medicare beneficiaries. The commenter further expressed concern that Shared Savings Program necessarily involved incentives to stint on care. Therefore, the commenter asserted, it is critical that CMS incorporate into the final rule robust and explicit protections similar to those that Medicare has traditionally found necessary to ensure that no Medicare beneficiaries are harmed by the program.

Response: We disagree with the commenter's assertion that the Shared Savings Program ''necessarily involves incentives to stint on care.'' This final rule incorporates a variety of program protections, and we intend to monitor the program closely for fraud and abuse. Elsewhere in this issue of the **Federal Register,** HHS OIG and CMS have jointly issued an interim final rule with comment period regarding issues related to the physician self-referral law, anti-kickback statute, and certain civil monetary penalty law provisions. See that interim final rule with comment period for a consideration of comments related to the physician self-referral law, anti-kickback statute, and certain civil monetary penalty law provisions. We believe the waivers will balance effectively the need for innovation and flexibility in the Shared Savings Program with protections for beneficiaries and the Medicare program.

Final Decision: We are finalizing the requirement to prohibit ACOs, their ACO participants, their ACO providers/suppliers, from conditioning participation in the ACO on referrals of Federal health care program business to the ACO, its ACO participants, or its ACO providers/suppliers for services they know or should know are being provided to beneficiaries who are not assigned to the ACO. For the reasons discussed above, we are modifying our final rule to prohibit limiting or restricting referrals of patients to ACO participants or ACO providers/suppliers within the same ACO, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the judgment of the referring party.

f. Record Retention

In order to ensure that we have the information necessary to conduct appropriate monitoring and oversight of ACOs, we proposed that ACOs, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must retain records of their activities under the Shared Savings Program for a sufficient period of time to allow the government to conduct the appropriate audits, evaluations, investigations and inspections of their activities. For a complete discussion of these proposals, please refer to the proposed rule published April 7, 2011 (76 FR 19651).

Comment: Commenters agreed with the record retention and audit proposals but recommended that the six year record retention requirement be limited to disputes involving only the ACO, not its ACO participants, its ACO providers/suppliers, or other contracted entities. In addition, commenters expressed concern that the record retention requirements would continue to apply even after the ACO has dissolved. The commenter asked CMS to address the question of which party is liable for any issues that surface after the ACO no longer exists. Commenters suggested that the responsibility should be divided among the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

Response: We see no reason to limit the 6-year record retention provision as suggested by the commenter. We note that the proposed record retention and audit requirements are consistent with other Medicare programs, such as MA. In order to provide ACOs with flexibility, we decline to specify how ACOs, ACO participants, ACO providers/suppliers, or other

individuals or entities performing functions or services related to ACO activities will develop a records retention plan or apportion responsibility for record retention in the event the ACO dissolves prior to conclusion of the audit and record retention period. We anticipate that the ACO and the entities participating in the ACO will develop policies related to audit and record retention that address the needs of the ACO's operations while retaining records and permitting access to records for audit for the required time period.

Final Decision: We finalize our proposed audit and record retention requirements (§ 425.314) with the clarification that, as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination. We further clarify that, consistent with our authority, the record retention requirements in this rule do not limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the records of the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

g. Beneficiary Inducements

As noted in section II.B of this final rule, section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to promote * * * patient engagement.'' We described in the proposed rule that the term ''patient engagement'' is the active participation of patients and their families in the process of making medical decisions. Patient engagement is an important part of motivating and encouraging more active participation by beneficiaries in their care delivery.

Comment: Some commenters noted that beneficiary engagement and coordination of care could be enhanced by providing additional incentives to beneficiaries to motivate and encourage them to be actively involved in their care. Some commenters suggested that one way to promote patient engagement would be to offer beneficiaries incentives to encourage health awareness. One commenter gave the example of supplying scales to beneficiaries with CHF to help them better manage this chronic disease.

On the other hand, one commenter recommended that CMS and the OIG closely monitor ACOs to ensure that exceptions to the physician self-referral laws are not abused; and prohibit ACOs from waiving co-pays, giving deep discounts, or offering other incentives to ACO patients in order to induce them to receive services within the ACO. One commenter expressed concern with his experience that network providers use coercive methods to keep patients ''within network,'' or to ensure that the patients receive care from a particular provider or supplier, which may be owned by the physician or his or her employer. The commenter asserted that such methods may include a physician refusal to order services, or to continue to serve as the patient's treating physician. The commenter asked CMS to make sure such methods will not be permitted and to describe how patient freedom of choice will be enforced.

Others recommended that CMS prohibit the ACO from providing gifts, cash, or other remuneration as inducements for receiving services or remaining assigned to an ACO or with a particular ACO participant or ACO provider/supplier. Commenters stated that CMS should prohibit ACOs from waiving co-pays, giving deep discounts, or offering other incentives to ACO beneficiaries in order to incentivize them to receive services within the ACO.

Response: We agree with commenters that providing gifts, cash, or other remuneration to beneficiaries as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO should be prohibited.

This final rule therefore provides at § 425.304 that an ACO, its ACO participants, its ACO providers/suppliers, and other individuals and entities performing functions or services related to ACO activities are prohibited from providing gifts, cash, or other remuneration as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO.

However, we also believe that there are certain instances when an ACO, its ACO participants, and its ACO providers/suppliers may offer items or services to beneficiaries for free or below market value to encourage care coordination and encourage beneficiary health awareness. For this reason, and consistent with the joint CMS and OIG interim final rule with comment period published elsewhere in this issue of the **Federal Register** describing waivers of certain fraud and abuse authorities in connection with the Shared Savings Program, we are adding a provision at § 425.304 to provide that an ACO, its ACO participants, or its ACO providers/suppliers may provide to beneficiaries items or services for free or below fair-market-value if all the following conditions are met:

- The ACO remains in good standing under its participation agreement.
- 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.

For example, an ACO provider may give blood pressure monitors to patients with hypertension in order to encourage regular blood pressure monitoring and thus educate and engage beneficiaries to be more proactive in their disease management. In this instance, such a gift would not be considered an improper inducement to encourage the beneficiary to remain with an ACO, ACO participant, or ACO provider/supplier. However, this final rule would prohibit an ACO, ACO participant, or ACO provider/supplier, or another individual or entity performing functions or services related to ACO activities from offering monetary or other gifts (for example: Baseball tickets, jewelry, household items, gift certificates for non-health care related retail items) that can be used for purposes other than direct health and care related purposes. We intend to interpret § 425.304 consistent with the joint OIG/CMS interim final rule referenced above, which contains additional discussion and information on the subject.

5. Terminating an ACO Agreement

a. Reasons for Termination of an ACO's Agreement

There are a number of important statutory requirements that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. In addition, using our authority under section 1899(a)(1)(A) of the Act, we proposed additional regulatory criteria that ACOs must satisfy to enter and remain in the Shared Savings Program. Although sections 1899(d)(3) and (d)(4) of the Act authorize termination for avoidance of at-risk beneficiaries and for failure to meet the quality standards, we do not believe that Congress intended the remainder of the regulatory scheme to be unenforceable. We believe that the Shared Savings Program participation agreement with an ACO should be contingent upon that ACO continuing to meet the requirements for eligibility and

other program requirements. Accordingly, we proposed that the participation agreement would require the ACO to comply with the requirements of the Shared Savings Program in order to participate in the program. In addition, we proposed that we would monitor compliance with eligibility requirements and that we could discretion terminate an agreement with an ACO before the end of the term of its agreement for a number of reasons which can be reviewed in detail at (76 FR 19649).

Furthermore, we proposed that an ACO may voluntarily terminate its agreement. We believe it is appropriate that an ACO should provide notice if it elects to terminate its participation in the Shared Savings Program. Accordingly, we proposed to require an ACO to provide us with a 60-day notice if it chooses to terminate its agreement. We also proposed that the ACO would be required to notify us of its decision to terminate its participation in the Shared Savings Program and would also be required to notify all of its ACO participants and ACO providers/suppliers, who would in turn be required to notify beneficiaries in a timely manner of the ACO's decision to withdraw from the Shared Savings Program. We also proposed that, as described in section II.F.13. of the proposed rule (76 FR 19615), the ACO would forfeit its mandatory proposed 25 percent withhold of shared savings.

Comment: Commenters stated that 60-day notices for an ACO to exercise its right to terminate its agreement is not appropriate in the commercial market and allowing an ACO to terminate the agreement with such limited notice, especially in the first and second year of a one-sided only risk agreement, will add costs to the system rather than reduce them. These commenters are concerned that allowing such short notice may permit increased potential for ''gaming'' in that ACOs easily terminate when they are experiencing losses.

Response: We appreciate all the commenters concerns, however, we believe there is a distinction between the MA and the Shared Savings Programs which does not require the same restrictions. Unlike managed care plans, ACOs do not need to transition beneficiaries to another plan. Moreover, as discussed previously in this section, and in response to comments, we are eliminating the requirement for the ACO to notify beneficiaries that the ACO, ACO participants or ACO providers/suppliers are no longer participating in the program. Thus, ACOs are only required to notify CMS and their ACO participants and ACO providers/suppliers that they are terminating their agreement.

Comment: Some commenters stated that the myriad reasons proposed for termination pose too much risk for providers to participate. Specifically, commenters disagreed with termination of an ACO's agreement for use of improper or unapproved marketing materials, underperforming on quality performance standard or failure to submit quality data, failure to submit payment of losses in a timely manner and changes in the ACO's leadership and management structure. A few commenters suggested that CMS does not have the authority to terminate an agreement for reasons other than avoidance of at-risk beneficiaries and failure to meet quality standards.

In contrast, several commenters believe CMS should expand the reasons for termination so that they are consistent with the MA program. Commenters suggested ACO should be terminated if the number of assigned beneficiaries to the ACO fall below 5,000 in any given month; felony, conviction or indictment of any owner of the parent of the ACO; OIG exclusion, or lack of meaningful beneficiary participation in the ACO.

Response: We believe it is necessary to be able to terminate ACOs for failure to comply with the regulations because that is an important protection for beneficiaries and against abuse. As discussed in this section, we intend to use a variety of sanctions such as warning letters and CAPs to address noncompliance, at CMS' sole discretion, in addition to termination. Termination is only one option and CAPs may be sufficient to certain correct types of noncompliance; situations where noncompliance is more serious may require immediate termination.

It is our intent to ensure beneficiary and program protections (especially in light of the fraud waivers) while minimizing burden for ACOs interested in participating in the program. Concurrently with our proposed rule, CMS and the Office of Inspector General published a Joint Notice on Waiver Designs in Connection with the Medicare Shared Savings Program that proposed certain waivers of the physician self-referral law, anti-kickback statute, and civil monetary penalties law. Elsewhere in this issue of the **Federal Register,** CMS and OIG have published final interim waivers of those laws. We are modifying this proposal to address how any continuing violations of those laws will affect the termination provisions. Specifically, we have clarified that ACOs may be terminated for violations of these three laws only to the extent that the laws are not waived. We have also clarified that ACOs may be terminated if their participants submit false certifications to CMS; we remind them that such false certifications may also trigger liability under the False Claims Act.

We decline to adopt commenters' suggestion that we expand the reasons for termination so they are consistent with the MA program. We believe there are important distinctions between the MA and the Shared Savings Program, as discussed throughout this final rule. It is our goal to create policies that ensure beneficiary and program protections while balancing burden imposed on ACOs.

We believe that meeting the 5,000 beneficiary threshold is an important eligibility requirement as discussed in section II.B. of this final rule and that ACO would no longer meet those requirements if it fall below 5,000 beneficiaries. An ACO assignment that falls below 5,000 would fail to meet the eligibility as outlined in this final rule, and therefore would be terminated under our proposal to terminate ACOs that fail to meet eligibility requirements. We would use various monitoring methods discussed in this section such as quarterly aggregated reports to determine if ACOs no longer meet the 5,000 beneficiary threshold. This comment and others raise a good point that despite the list proposed in the proposed rule, there are a number of reasons why it may be desirable to terminate an ACO for non-compliance with program requirements and for failure to meet eligibility. Therefore, we will generalize the reasons why an ACO may be terminated to include non-compliance with program requirements and for failure to meet requirements necessary for eligibility.

Comment: Some commenters suggested we give ACOs an opportunity to explain why they are not in compliance with program rules before terminating an ACO agreement.

Response: Where appropriate, we will work with the ACO to understand why the noncompliance occurred so that we can develop an effective CAP and monitoring technique. However, in instances where we believe the circumstances are more serious or pose risk of harm to beneficiaries or access to care, we reserve the right to terminate a participation agreement immediately without providing an ACO the opportunity for a CAP or warning notice.

Final Decision: We are therefore finalizing our proposal under § 425.218 for terminating an ACO and for taking

certain actions before termination under § 425.216. Specifically, CMS may terminate an ACO's agreement for non-compliance with the requirements of the Shared Savings Program, which includes maintaining eligibility. Examples include termination for avoidance of at-risk beneficiaries, failure to meet quality performance standards as previously described previously. We have modified this final rule to retain the right to terminate an ACO's agreement immediately for violations we determine are more serious.

Additionally, as discussed in this section, we are finalizing our proposal to use a variety of sanctions such as warning letters and CAPs to address non-compliance, as CMS' sole discretion, in addition to termination. We are clarifying that we will work with ACOs where appropriate to understand why the noncompliance occurred and work to develop an effective CAP. Also, we wish to clarify that certain personnel changes in leadership and management would not necessarily result in termination, for example, one qualified medical director replacing the initial qualified medical director, provided the ACO continued to meet the eligibility criteria and remained able to perform all of the required functions of an ACO participating in the Shared Savings Program. However, as proposed, changes in leadership and management structures such that the ACO no longer meets eligibility to participate in the program, for example, no longer having a formal legal structure, would be grounds for termination. Finally, we have modified our proposal to clarify that CMS will provide the ACO with notice of termination.

Further, we would like to clarify that consistent with our proposal to terminate an ACO in the event sanctions or other actions are taken against an ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, by an accrediting organization, or by a State, Federal, or local government agency, an ACO agreement may be terminated if its providers are excluded by the OIG or have their privileges to participate in Medicare revoked. We are also clarifying that demonstrating meaningful beneficiary participation is a requirement for eligibility and as such, failure to adequately notify beneficiaries of participation in the program would constitute grounds for terminating the ACO.

We are also clarifying that if an ACO has violated the antitrust laws or the fraud and abuse authorities (except to the extent these laws are waived by the Secretary under section 1899(f) of the Act), the ACO's eligibility to participate in the Shared Savings Program will have to be reassessed by CMS. For example, if an antitrust agency disbands the ACO for violation of antitrust laws, the ACO no longer exists as the applicant that was approved for a participation agreement and may therefore be terminated.

After taking all comments into consideration, we are finalizing our rule that ACOs may voluntarily terminate and will be required to provide CMS and all of its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities with a 60-day notice of its decision to terminate its participation in the Shared Savings Program. We are clarifying that ACOs that terminate their participation agreement early will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement because it failed to complete the entire performance year by which we calculate shared savings payments (§ 425.316(c)(5)). After taking into consideration commenters' concerns and to reduce burden on ACOs, this final rule provides that an ACO would not be required to notify beneficiaries of the ACO's decision to withdraw from the Shared Savings Program. We have also not finalized our proposal to require the ACO to forfeit its mandatory proposed 25 percent withholding of shared savings if its agreement is terminated before the term is completed.

b. Corrective Action Plans

In the proposed rule, we proposed that, at our sole discretion, CMS could require the ACO to produce a corrective action plan (CAP) prior to termination for minor violations that we do not believe pose no immediate risk of harm to beneficiaries or impact care. Additionally, we proposed that an ACO must submit a CAP for our approval by the deadline indicated on the notice of violation. Under our proposal, the CAP would address what actions the ACO will take to ensure that the ACO, ACO participants, and other individuals or entities performing functions or services related to ACO activities would correct any deficiencies to remain in compliance with Shared Savings Program requirements. We proposed that the CAP would be implemented as approved, and that the ACO's performance would be monitored during the CAP process. We further proposed that failure of the ACO to submit a CAP by the requested deadline, obtain approval for, or implement a CAP may result in termination of the agreement. Similarly, failure of the ACO to demonstrate improved performance upon completion of the CAP may result in termination. We also proposed that the ACO would not receive shared savings payments while it is under a CAP regardless of the performance period in question and that the ACO would not be eligible to earn any shared savings for the period during which it is under a CAP.

Comment: We received very few comments regarding the CAP process. There were no comments received that opposed the CAP process.

Final Decision: We are finalizing our proposal under which we may require an ACO to produce a corrective action plan (CAP) for violations that we consider minor in nature and pose no immediate risk of harm to beneficiaries or impact on care.

c. Future Participation of Previously Terminated Program Participants

In our proposed rule, we discussed how ACOs would be handled that terminate their agreement to participate in the Shared Savings Program, are terminated from the Program, or underperform and do not achieve savings during the first agreement period (section II.H.3. of the proposed (76 FR 19653)) but wish to participate in the Program for an additional performance period.

We proposed that potential ACOs disclose to CMS as part of its application whether the ACO, its ACO participants, or its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities have participated in the program under the same or a different name, and specify whether the entity or person was terminated or withdrew voluntarily from the program. If the entity or person was previously terminated from the program, the applicant must identify the cause of termination and what safeguards are now in place to enable the prospective ACO to participate in the program and complete the term of the new agreement. We proposed that terminated ACOs may not begin another agreement period until the original agreement period had lapsed. (See (76 FR 19653), for discussion of our proposal to prohibit ACO's which demonstrate a net loss in their first agreement period from reapplying to participate in the Shared Savings Program.) In addition, consistent with our proposal that ACOs may only have one agreement under the one-sided model, we proposed that previously

terminated ACOs that wish to reenter the program must do so under the two-sided model.

Comment: Some commenters indicated ACOs may have difficulty achieving net gains during their first agreement period. Others projected that it will take several years for an ACO to become fully operational. Commenters suggested that the prospect of being disqualified from the program before recovering the start-up costs required to form an ACO will deter providers from participating. Several commenters were supportive of allowing well-intentioned ACOs, terminated from the program, to reapply. In particular, one commenter recommended a more flexible approach in the final rule that does not penalize well-meaning, otherwise acceptable ACO who might have had understandable difficulties.

Response: We must ensure our policy on subsequent participation in the Shared Savings Program does not provide a second chance for under-performing organizations or for providers or suppliers who have been terminated for failing to meet program integrity or other requirements. We believe that this is an important protection for beneficiaries and the program. We do believe the commenter's standard of allowing ''well intentioned'' ACOs to reapply is easily enforced.

We have considered public comments received on this policy, however, we 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. We are therefore finalizing our rule such that ACOs who were previously terminated through enforcement action or voluntarily that wish to re-enter the Shared Savings Program may do so at the end of their initial agreement period. We note that excluded individuals or entities would not be permitted to participate in the Shared Savings Program unless and until their reinstatement. An ACO that was previously terminated may reenter the program only under the two-sided model unless it was terminated less than half way through its agreement under the one-sided model in which case it will be allowed to re-enter the one-sided model. An ACO that was terminated more than half way through its agreement will only have the option of entering in Track 2. Such an ACO must describe the reason for termination of its initial agreement and what safeguards are now in place to enable the prospective ACO to participate in the program for the full term of their participation agreement. We believe it is important beneficiary and program protections to limit participation in the program to providers and suppliers who are dedicated to the goals of the program.

Final Decision: We will finalize our proposal that the ACO disclose to us whether the ACO, its ACO participants, or its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, have participated in the program under the same or a different name, and specify whether it was terminated or withdrew voluntarily from the program. If the ACO, its ACO participants or ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities were previously terminated from the program, the applicant must identify the cause of termination and what safeguards are now in place to enable the prospective ACO to participate in the program for the full period of the initial term of agreement. We will consider this information in determining whether an ACO should be approved to participate in the program.

ACOs that are terminated from the program will be afforded the opportunity to re-apply to participate in the shared savings again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated. An ACO that was terminated less than half way through its agreement under the one-sided model will be allowed to re-enter the one-sided model at the conclusion of the term of their original agreement. ACOs that were terminated more than half way through its agreement will only have the option of entering under Track 2 at the conclusion of the term of their original agreement.

6. Reconsideration Review Process

In the proposed rule, we outlined certain actions specified in section 1899(g) of the Act for which there shall be no administrative or judicial review. However, we stated that it is important to establish a fair administrative process by which ACOs may request review of other decisions, such as the denial of an application to participate in the program or the termination of an existing participation agreement for reasons other than those exempted by statute. For a full discussion of our proposals and rationale, see the proposed rule published April 7, 2011 (76 FR 19627).

Comment: Commenters expressed concern that the statutory exceptions to administrative review should be construed narrowly so that additional reasons for administrative review are allowed and that the proposed timeframe to request a review (15 days) is too short. Commenters also expressed concern with the fairness of the reconsideration review process since CMS is not an independent party. Commenters specifically recommended that CMS—

- Establish an appeals and grievance system for patients and providers when care is compromised;
- Review all cases in which an ACO requests reconsideration; and
- Establish a review process through an independent party.

Response: The decisions excluded from the reconsideration review process are consistent with section 1899(g) of the Act. Our reconsideration review process was built on our experience with established, effective, and well accepted procedures used in other Medicare programs. The reconsideration review allows for significant procedural due process for all parties, a clear and easily understood linear process, and reviews by independent CMS officials. The timeframe allowed to request review under the reconsideration review process is consistent with the MA (§ 422.622) and Part D (§ 423.651) programs which both provide 15 calendar days after receipt of the notice of determination to request review. We agree that the reconsideration review should be conducted by an independent reviewer. The process as proposed allows the ACO the opportunity to have a reconsideration review conducted by an independent reviewer who was not involved with any previous determination including both the initial and review stage of the reconsideration. We also believe that we have proposed several monitoring tools that will ensure beneficiary protections and as a result, we do not believe it is necessary to establish a separate grievance process for ACOs.

Final Decision: After consideration of the comments received and for the reasons discussed previously, we are finalizing the reconsideration review process as proposed, with the exception of our decision to eliminate the specific provision related to review of determinations made by a reviewing antitrust agency as no longer applicable in light of the revisions to our procedures for Antitrust review, which are discussed in section II.C. of this final rule. We are clarifying that when we stated ''if any of the parties disagree with the recommendation of the reconsideration, they may request an on the record review,'' we were referring to both CMS and the ACO.

III. Collection of Information Requirements

As stated in section 3022 of the ACA, Chapter 35 of title 44, United States Code, shall not apply to the MSSP. Consequently, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget.

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 2011, that threshold is approximately $136 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 $136 million in any one year. We acknowledge that there will be costs borne by the private sector, as discussed in this regulatory impact section, in order to participate in this program; however, participation is voluntary and is not mandated.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe that there is anything in this final rule that either explicitly or implicitly pre-empts any State law, and furthermore we do not believe that this final rule will have a substantial direct effect on State or local governments, preempt State law, or otherwise have Federalism implications.

B. Statement of Need

This final rule is necessary to implement section 3022 of the Affordable Care Act which amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding a new section 1899 to establish a Shared Savings Program that promotes accountability for a patient population, coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Section 1889(a)(1) of the Act requires the Secretary to establish this program not later than January 1, 2012. Also, section 1889(a)(1)(A) of the Act states that under this program, ''groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (referred to * * * as an 'ACO')''; and section 1889(a)(1)(B) of the Act provides that ''ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings * * *.''

The Shared Savings Program is a new approach to the delivery of health care aimed at reducing fragmentation, improving population health, and lowering growth in overall health care costs.

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. Consequently, in accordance with the authority granted to the Secretary under sections 1899(d) and 1899(i) of the Act, we looked at creating both a shared savings model (one-sided) and a shared savings/losses model (two-sided). The sharing parameters under the two options are balanced so as to provide greater reward for organizations that accept risk while maintaining sufficient incentive to encourage providers to participate in the one-sided model, which provides an entry point to risk-oriented models.

C. Overall Impact

As detailed in Table 8, we estimate a total aggregate median impact of $470 million in net Federal savings for calendar years (CY) 2012 through 2015 from the implementation of the Shared Savings Program. The 10th and 90th percentiles of the estimate distribution, for the same time period, yields a net savings of $940 million and $0 million, respectively. These estimated impacts represent the effect on Federal transfers. Median estimated Federal savings are somewhat less than the estimate published for the proposed rule (estimated $510 million net savings through 2014) due in part to increased program generosity, led by first-dollar (below benchmark) sharing. This, combined with the easing of a number of program requirements and burdens, expands our expected range of participation, resulting in a somewhat greater median net savings amidst a wider stochastic projection range.

Furthermore, we estimate a total aggregate median impact of $1.31 billion in bonus payments to participating ACOs in the Shared Savings Program for CYs 2012 through 2015. The 10th and 90th percentiles of the estimate distribution, for the same time period, yield a bonus payment to ACOs of $890 million and $1.9 billion, respectively.

We estimate the aggregate cost associated with the start-up investment of ACOs participating in the Shared Savings Program will range from $29 million to $157 million. The program's first agreement period has been expanded by up to 6 to 9 months, rewarding ACOs who enter the program early in 2012 with a longer agreement period under their initial benchmark, while also accommodating ACOs that might require an additional year (or partial year) of preparation. Furthermore, aggregate ongoing annual operating costs for the participating ACOs are estimated to range from $63 million to $342 million. Both start-up investment and ongoing annual operating cost ranges utilize an anticipated participation rate of 50 to 270 ACOs in the Shared Savings Program. Lastly, when utilizing the anticipated mean participation rate of ACOs in the Shared Savings Program, this yields an estimated aggregate average start-up investment and ongoing annual operating costs of $451 million for CYs 2012 through 2015. Therefore, as illustrated in Table 8, for CYs 2012 through 2015 the total median ACO bonus payments of $1.31 billion

coupled with the aggregate average start-up investment and ongoing annual operating cost of $451 million, incurred at the mean participation rate of ACOs in the Shared Savings Program, result in an estimated benefit-cost ratio of 2.9.

In addition to rewarding ACOs who enter the program early in 2012 with a longer effective agreement, while also accommodating ACOs that might require an additional year (or partial year) of preparation, the Shared Savings Program will also benefit beneficiaries since the program requires ACOs to be accountable for Medicare beneficiaries, improve the coordination of FFS items and services, and invest in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrate a dedication and focus toward patient-centered care. 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 8—ESTIMATED NET FEDERAL SAVINGS, COSTS AND BENEFITS, CYS 2012 THROUGH 2015

	CY 2012	CY 2013	CY 2014	CY 2015	CYs (2012–2015)
Net Federal Savings:					
10th Percentile	−$30 Million	−$20 Million	$10 Million	$0 Million	$0 Million.
Median	$20 Million	$90 Million	$160 Million	$190 Million	$470 Million.
90th Percentile	$70 Million	$210 Million	$320 Million	$370 Million	$940 Million.
ACO Bonus Payments:					
10th Percentile	$60 Million	$180 Million	$280 Million	$360 Million	$890 Million.
Median	$100 Million	$280 Million	$410 Million	$520 Million	$1,310 Million.
90th Percentile	$170 Million	$420 Million	$600 Million	$740 Million	$1,900 Million.
Costs	The estimated start-up investment costs for participating ACOs range from $29 million to $157 million, with annual ongoing costs ranging from $63 million to $342 million, for the anticipated range of 50 to 270 participating ACOs. With the mean participation of ACOs, the estimated aggregate average start-up investment and four year operating costs is $451 million.				
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 percentiles estimated for the total four year impact, in the column labeled CYs 2012–2015, due to the annual and overall distributions being constructed independently.

Participating ACOs will have the opportunity to earn shared savings payments by reducing Medicare expenditure growth for their assigned beneficiaries below specified target thresholds or benchmarks while simultaneously meeting quality performance measures. An ACO could initially opt for one of two program tracks. The first option (one-sided model) offers eligibility for shared savings payments in all years without the risk of being responsible for repaying any losses if actual expenditures exceed the benchmark. Combined with rolling enrollments into the program in 2012, ACOs will have options to ease their transition toward responsibility for quality of care improvement and the total cost of care for the beneficiaries they serve. The second option (two-sided model) provides an opportunity for receiving a higher percentage of shared savings for all years of the agreement period, but with potential liability in each of the agreement years for annual expenditures that exceed the benchmark, thereby increasing associated risk.

There is substantial uncertainty as to the number of ACOs that will participate in the program, their characteristics, provider and supplier response to the financial incentives offered by the program, 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 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 on Medicare expenditures.

To best reflect these uncertainties, we designed 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 5,000 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 8. 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 Shared Savings Program, recognizing the uncertainty inherent in a new program with uncertain responses. The full distribution illustrates the uncertainty surrounding the mean or median financial impact from the simulation.

As detailed in Table 9, the median estimate involves a combination of: (1) Reduced actual Medicare expenditures due to more efficient care; (2) shared savings payments to ACOs; and (3) payments to CMS for shared losses when actual expenditures exceed the benchmark, resulting in a projected total of $470 million in net savings over CYs 2012 through 2015. Greater participation is estimated due to the option for a longer 42 or 45 month agreement period, gentler transition period, and greater generosity provided. The extra year also amplifies our estimated savings and cost totals.

A net savings (costs) occurs when the payment of earned and unearned

shared-savings bonuses (less penalties collected) resulting from: (1) Reductions in spending; (2) program design; and (3) random group claim fluctuation, in total are less than (greater than) assumed savings from reductions in expenditures.

As the actual number of participating ACOs and their characteristics become known, the range of financial outcomes will narrow. Similarly, as data become available on the initial differences between actual expenditures and the target expenditures reflected in ACO benchmarks, it will be possible to evaluate the financial effects with greater certainty. The estimate distribution shown in Table 9 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 implementation.

D. Anticipated Effects

1. Effects on the Medicare Program

As a voluntary program involving an innovative and complex mix of financial incentives for quality of care and efficiency gains within FFS Medicare, the Shared Savings Program could result in a wide range of possible outcomes. While examples exist across the healthcare marketplace for risk-sharing arrangements leading to efficiency gains, a one-sided model would presumably provide a weaker incentive to ACOs than other approaches. Track 2 introduces downside risk while offering a lower minimum savings rate and a greater sharing percentage, all of which enhance the incentive for efficiency while protecting the Trust Funds against losses for fluctuation or other exogenous factors. It is possible that participation in Track 1 might enable such ACOs to gain the experience necessary to take on risk in a subsequent 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 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.

Even ACOs that opt for Track 2 could eventually terminate their agreement if they anticipate that efforts to improve efficiency are overshadowed by their particular market circumstances. (Under section 1899(d) of the Act, we update ACO benchmarks by the estimated annual increase in the absolute amount of national average Medicare Part A and Part B expenditures, expressed as a flat dollar amount for each year. As a result, the updates to ACO benchmarks in percentage terms will be higher in low-cost areas of the country and lower in high-cost areas.) This scenario could contribute to selective program participation by ACOs favored by the national flat-dollar growth target, or favored by other unforeseen biases affecting performance.

While shared FFS savings, even with optional liability for a portion of excess expenditures, offers less incentive to reduce costs than, say, full capitation, it still represents a new incentive for efficiency. Shared-savings (and potential liabilities) will have varying degrees of influence on hospitals, primary physicians, specialty physicians, and other providers. The expectation is for different ACOs to comprise a varying mix of these providers and suppliers. And 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), many potential ACOs might need more than 3 years to achieve comprehensive efficiency gains. Challenges include identification of assigned beneficiaries, coordinating care furnished by providers and suppliers outside the ACO, lack of similar contracts with other payers, achieving buy-in from ACO providers/suppliers, and the extent to which possible future shared savings or losses will affect the perceived value of immediate FFS revenue for providers and suppliers participating in an ACO.

While there remains great uncertainty for the aggregate financial impact of the program, the impact on quality, as will be measured and reported, is likely to show gains for most participating ACOs over the course of their agreement.

Comment: One commenter recommended that we include further detail regarding the beneficiary population expected to be assigned to ACOs participating in the Shared Savings Program, including characteristics of ethnicity and gender, and further requested that we provide baseline per capita FFS expenditures. Another commenter requested that we analyze the average expenditures for beneficiaries in States with low, median, and high average expenditures, were they assigned to an ACO participating in the Shared Savings Program achieving maximum shared-savings, were they enrolled in a Medicare Advantage organization of various quality star ratings, or were they simply in traditional Medicare.

Response: Due to the great uncertainty regarding the quantity and composition of ACOs that will participate in the Shared Savings Program, such estimates of the demographic characteristics or per capita expenditures of affected beneficiaries are not currently feasible. Even were we confident of specific markets that were likely to generate ACOs, we would require the mix of TINs that would be aggregated to form the basis of assignment to such potential ACOs in order to estimate any potential differences in the demographic characteristics for all ACO-assigned patients relative to the greater FFS Medicare population, or to analyze differences in average expenditures relative to MA or traditional Medicare. Such expenditures could vary significantly based not only on geography but also an ACO's provider composition, which can mean ACOs in the same market may have widely varying baseline per capita expenditures for their assigned beneficiaries. Indeed, a stochastic model was chosen to illustrate such great uncertainty presented by voluntary participation in a new and complex program. However, we agree that such analysis would be beneficial within future evaluations based on actual program experience.

a. Assumptions and Uncertainties

We sought input 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. Also, subsequent to publication of the proposed rule, we studied rule comments, expert reactions, and letters of intent for the Innovation Center Pioneer ACO Model. The assumptions ultimately identified and stochastically modeled include the following:

- Number of participating ACO provider groups, 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 under Track 2.
- Participating ACOs' current level of integration and preparedness for improving the quality and efficiency of care delivery.
- Baseline per-capita costs for prospective 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 ACO 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.

Overall we assumed 1 to 5 million Medicare beneficiaries would align with between 50 and 270 ACOs during the first four years of the program. We assumed ACOs to be equally likely to participate from markets exhibiting baseline per-capita FFS expenditures above, at, or below the national average, as opposed to our assumption for the proposed rule that ACOs would be more likely to form in high-cost markets. In addition, we assumed the level of savings generated by an ACO to positively correlate to the achieved quality performance score and resulting sharing percentage.

We anticipate a minority of ACOs—a more capable subset of the total program participation—will opt for Track 2 in the first agreement period, enabled by experience accepting risk for other populations and motivated by a lower minimum savings rate and greater sharing percentage. However, most participating ACOs are expected to choose Track 1 in order 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) build organizational experience to achieve a per-capita cost target as presented by the program's unique benchmark methodology.

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). The benchmark or expenditure target effectively serves as the only 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 9 shows the distribution of the estimated net financial impact for the 5,000 stochastically generated trials. (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 losses collected for ACOs that accepted risk and have actual expenditures exceeding their benchmark.

The median estimate of the Shared Savings Program financial impact for calendar years 2012 through 2015 is a net Federal savings of $470 million. This amount represents the ''best estimate'' of the financial impact of the Shared Savings Program initiative during the agreement period. It is important to note, however, the relatively wide range of possible outcomes. Overall, 90 percent of the stochastic trials resulted in net program savings, and the remaining 10 percent represented cost increases. The 10th and 90th percentiles of the estimated distribution show net savings of $940 million and a net cost of $ zero million, respectively, suggesting a 10 percent likelihood that the actual impact would fall outside respective percentile amounts. In the extreme scenarios, the results were as large as $2.0 billion in savings or $1.1 billion in costs. Relative to the proposed rule, the final rule projections reflect greater generosity (and cost to Medicare) offset by greater participation over an extended agreement period, leading to a higher median net savings but also a wider stochastic range than we would now estimate for the proposed rule over the same period. (Market response to the proposed rule causes us to decrease the participation levels we would assume for the originally proposed program design.)

The stochastic model and resulting financial estimates were prepared by the CMS Office of the Actuary (OACT). The median result of $470 million in savings is a reasonable ''point estimate'' of the impact of the Shared Savings Program provision in current law, as it would be implemented through this final rule. However, we emphasize the possibility of outcomes differing substantially from the median estimate, as illustrated by the estimate distribution. With additional data on the actual number and characteristics of participating ACOs, we can estimate the financial impact with greater precision.

The projections assume the assignment of roughly 1 to 5 million beneficiaries to participating ACOs during the first program agreement period. 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, Shared Savings Program savings or costs would result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

TABLE 9—STOCHASTIC DISTRIBUTION FOR THE ESTIMATED NET SAVINGS (–) OR COSTS (+), CYs 2012 THROUGH 2015
($ millions)

Table 10 shows the median estimated financial effects for the Shared Savings Program initiative, and the associated 10th and 90th percentile ranges, broken out during the first agreement period. Net savings (characterized by a negative net impact on Federal outlays) are expected to be marginal in 2012 ($20 million) due to gradual enrollment assumed over that first year as well as the assumption that cost-saving initiatives will require time for maturation. In calendar years 2013 through 2015 net savings are expected to grow as maturing cost-saving effectiveness is partially offset by increasing cost from growing variation in the accuracy of updated national targets compared to actual local growth. As a result, the projections for CYs 2013 through 2015 cover a wider range of possible outcomes, reflecting a growing dependence on uncertain assumptions for savings and expenditure growth variation relative to the national average. We note that the percentiles are tabulated for each year separately, and therefore the overall net impact distribution (Table 9) will not necessarily exactly match the sum of distributions for each distinct year.

TABLE 10—STOCHASTIC DISTRIBUTION FOR ESTIMATED FEDERAL NET SAVINGS (–) OR COSTS (+), CYs 2012 THROUGH 2015
($ MILLIONS)

	2012	2013	2014	2015
▲ 90th %-ile	$30	$20	-$10	$0
■ median	-$20	-$90	-$160	-$190
◆ 10th %-ile	-$70	-$210	-$320	-$370

c. Further Consideration

The impact analysis shown is only for the first agreement period. Beyond this initial period, there is additional uncertainty, in significant part because the rules governing subsequent Shared Savings Program agreement periods have not yet been developed. In addition, uncertainties exist in the short and long term regarding providers' responses to the program. For example, a voluntary program may eventually draw selective participation by ACOs that develop an ability to predict a favorable bias in the savings formula. However, ACOs that participate in the program during the first agreement period may foster significant improvements in the quality and cost-efficiency of health care delivery, leading to broader use of these techniques nationwide and accelerated adoption of risk-sharing arrangements (such as partial capitation, bundled payments, etc.). These changes could result in significant efficiency gains in FFS Medicare. The stochastic model for the first agreement period of the program does not incorporate either of these longer-run scenarios, but both remain possibilities. At this time, an impact estimate expanded to include performance beyond the initial agreement period would likely entail a significantly wider range of possible outcomes. The results of the first performance cycle, however, will help inform estimates of the ongoing financial effects of the Shared Savings Program.

2. Impact on Beneficiaries

We anticipate the Shared Savings Program will benefit beneficiaries because the intent of the program is to require ACOs to be accountable for 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 that demonstrates a dedication and focus toward patient-centered care. This program does not affect the beneficiary's freedom of choice regarding providers or care since beneficiaries assigned to an ACO continue to be in the traditional Medicare program. Also, a requirement of ACO participation in the Shared Savings Program is reporting of, and successful performance related to, quality measures and patient-experience surveys. These aspects of the Shared Savings Program will encourage the provider and supplier community to focus on and deliver improved quality care. In addition to existing Medicare monitoring programs that are in place to protect beneficiaries, the Shared Savings Program will include monitoring and auditing processes to protect beneficiary choice as well as ensure that beneficiaries are receiving the appropriate care. As is discussed in more detail in the preamble, these processes include monitoring ACO avoidance of at-risk beneficiaries, assessing and providing follow up on beneficiary complaints, audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits) and analysis of quality performance.

More specifically, we believe that advantages for beneficiaries would be maximized as the ACO meets the mission of the Shared Savings Program, as established by the Affordable Care Act and embraces the goals of better health and experience of care for individuals, better health for populations and lower expenditure growth. The ACO's impact will be demonstrated by how effectively it delivers care as measured under the financial methodology outlined in section II.G. of this final rule, how well it improves and delivers high quality care outlined in the quality measurement and reporting methodology in section II.F. of this final rule, and in meeting program requirements for patient-centered care

outlined in the discussion of eligibility in section II.B. of this final rule.

Because ACOs are accountable for both the quality and overall cost of care provided to their assigned beneficiary population and must meet the quality performance standards prior to sharing any savings, they have new incentives to improve the health and well being of the beneficiaries they treat. ACOs will report on conditions and areas that are high prevalence and high cost in the Medicare population, such as chronic disease, ambulatory care sensitive conditions, care transitions and readmissions, and patient experience. We have observed that measuring quality and providing incentives can result in redesigned care processes that provide clinicians with actionable information on their patients at the point of care which can lead to improved patient care processes and outcomes. For example, the Medicare Physician Group Practice Demonstration Fact Sheet (CMS, July 2011) showed that over the first 4 years of the PGP Demonstration, physician groups increased their quality scores an average of 10 percentage points on the ten diabetes measures, 13 percentage points on the ten congestive heart failure measures, 6 percentage points on the seven coronary artery disease measures, 9 percentage points on the two cancer screening measures, and 3 percentage points on the three 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*).

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.

3. Impact on Providers and Suppliers

In order to participate in the program, we realize that there will be costs borne in building the organizational, financial and legal infrastructure that is required of an ACO as well as performing the tasks required (as discussed throughout the Preamble) of an eligible ACO, such as: Quality reporting, conducting patient surveys, and investment in infrastructure for effective care coordination. While provider and supplier participation in the Shared Savings Program will be voluntary, we have examined the potential costs of program participation.

In this final rule, we have revised many of the policies in the proposed rule, so as to allow for greater flexibility regarding the specific structure and requirements of an ACO, and we believe these changes will substantially reduce the burden associated with the infrastructure start-up and ongoing annual operating costs for participating ACOs in the Shared Savings Program. Significant modifications to reduce burden and cost for participating ACOs include offering flexibility in the: (1) Eligibility to participate in the Shared Savings Program; (2) program start date; (3) establishment of the agreement period; (4) governance and legal structure of an ACO; (5) quality performance standards and reporting on quality and cost measures; (6) adjustment to the benchmark and performance year expenditures; (7) shared savings determination and availability of first dollar savings; (8) transition to risk; (9) withholding 25 percent of shared savings; (10) timing for the evaluation of sharing savings (claims run-out); (11) antitrust review; and (12) timing for repayment of losses. Specific analyses regarding these significant final policy modifications are discussed in detail in section II. of this final rule.

Furthermore, beyond the statutory requirement that ACOs have at least 5,000 assigned Medicare beneficiaries, the size of ACOs will also vary in relation to beneficiary participation and associated costs. Due to the limited precedence for this program and uncertainty regarding the structure and strategies that the provider community will pursue in order to participate as an ACO, precise estimates of expected provider costs are difficult to create. An analysis produced by the Government Accountability Office (GAO) of first year total operating expenditures for participants of the Medicare PGP Demonstration varied greatly from $436,386 to $2,922,820, with the average for a physician group at $1,265,897 (Medicare Physician Payment: Care Coordination Programs Used in Demonstration Show Promise, but Wider Use of Payment Approach May Be Limited. GAO, February 2008). These costs (for groups which all had 200 or more physicians) include investments in infrastructure and information technology enhancements, management, quality reporting, and focused care coordination programs. The GAO also discovered that start-up investment expenditures in the PGP Demonstration varied between $82,573 and $917,398, with the average for a physician group at $489,354.

It is worth noting that the 10 participating physician groups in the demonstration were large compared with other physician practices in terms of annual medical revenues and non-physician staff. GAO claims that their larger relative size gave the 10 participating physician groups in the PGP Demonstration three size-related advantages over smaller physician practices. First, participants typically had institutional affiliations with an integrated delivery system, a general hospital, or a health insurance entity. Specifically 9 of the 10 participating physician groups were part of an integrated delivery system, 8 affiliated with a general hospital, and 5 affiliated with an entity that marketed a health insurance product. As a result of these affiliations, GAO claims that participating physician groups generally had greater access to relatively large amounts of financial capital needed to initiate or expand programs. The second advantage, GAO claims, the 10 large participating physician groups had over smaller physician practices is the increased probability of having or acquiring EHR systems, which was essential in participants' ability to gather data and track progress in meeting quality-of-care targets. For example, 8 of the 10 participating physician groups had an EHR in place before the demonstration began, and the 2 other participants, out of necessity, developed alternative methods for gathering patient data electronically. Lastly, GAO claims that the third size-related advantage that most of the 10 participating physician groups had over smaller physician practices was the larger groups' experience with other pay-for-performance systems prior to participating in the PGP Demonstration. That is, 8 of the 10 participants had previous experience with pay-for-performance programs initiated by private or public sector organizations. This experience, GAO concludes, may have eased their adjustment to the PGP Demonstration and allowed them greater initial and overall success. Therefore, we recognize that start-up and ongoing annual operating costs will vary greatly between ACOs for various reasons, including those related to the

experience, size and funding available to the participating ACO.

We use this 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 potential scope for aspiring participants. We expect that due to the difference in program requirements between the Shared Savings Program and the PGP Demonstration Project, and the potential variation in ACO size and structure, the PGP related costs may be a subset of the investment required by entities seeking participation in this program. However, we also recognize that potential advantageous key drivers for participating physician groups would include institutional affiliations that allow greater access to financial capital, access to and experience using EHR and other IT systems and experience with pay-for-performance programs. As a result, we continue to believe that the structure, maturity, and thus associated costs represented by those participants in the Medicare PGP Demonstration are most likely to represent the majority of anticipated ACOs participating in the Shared Savings Program. Lastly, we recognize that participating ACOs may involve Medicare and the commercial side within their business scope, thereby stratifying start-up investment and ongoing annual operating costs across various business segments, and not solely attributable to the Medicare Shared Savings Program.

We contacted several experienced provider organizations, private health plan network executives and investors involved with integrated delivery systems to assess the infrastructure costs associated in establishing a new ACO. As a result, we have revised our cost estimates relative to the proposed rule to reflect new information we learned regarding the start-up investment cost for an ACO. The ongoing annual operating costs presented in the proposed rule were validated and thus remain within the same range in the final rule. 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 $1.27 million in ongoing annual operating costs for an ACO participant in the Shared Savings Program. Lastly, assuming an expected range of ACOs participating in the Shared Savings Program of 50 to 270 ACOs yields an estimated start-up investment cost ranging from $29 million to $157 million, with ongoing annual operating costs ranging from $63 million to $342 million for CYs 2012 through 2015. When utilizing the anticipated mean participation rate of ACOs in the Shared Savings Program coupled with the average start-up investment and ongoing annual operating costs, this yields an estimated aggregate average start-up investment and ongoing annual operating costs of $451 million for the CYs 2012 through 2015.

While there will be a financial cost placed on ACOs in order to participate, there will be benefits to the respective organizations in the form of increased operational and healthcare delivery efficiency. 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 11, the estimated bonuses paid are a median of $1.31 billion during CYs 2012 through 2015, with $890 million and $1.90 billion reflecting the 10th and 90th percentiles. (Similar to the previously presented stochastic distributions, the distribution represents uncertainty given the range of expert opinion, rather than a true statistical probability distribution.) Therefore, the total median ACO bonus payments of $1.31 billion during CYs 2012 through 2015 coupled with the aggregate average start-up investment and ongoing annual operating cost of $451 million, incurred by the mean participation rate of ACOs in the Shared Savings Program during the same time period, yields a benefit-cost ratio of 2.9.

We expected an increased amount of total bonuses relative to the proposed rule due to a more favorable sharing CYs 2012 through 2015 arrangement and simplified requirements of participation, highlighted by first-dollar sharing and removal of year-3 risk in Track 1. The increase in bonuses is also in part due to the added participation expected as a result of these changes. Participating Track 2 ACOs will be assuming a risk of a financial penalty for failing to achieve savings (that is, if actual expenditures exceed the benchmark). At the median, we do not anticipate the collection of penalties during the first agreement period, with our 90th percentile projecting only $20 million in collected penalties. Penalties decrease relative to the proposed rule despite the increased participation assumptions. This is primarily due to the enhanced attractiveness of Track 1 relative to Track 2, as well as the removal of required risk from year three of Track 1. Due to the voluntary nature of this program, we expect the formation of ACOs by entities that aspire to receive benefits that outweigh their costs. ACOs that opt for Track 2 are expected to achieve significant savings in a shorter time period. We anticipate that not all ACOs 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.

TABLE 11—STOCHASTIC DISTRIBUTION FOR ESTIMATED ACO BONUS PAYMENTS, CYs 2012 THROUGH 2015

($ millions)

	2012	2013	2014	2015
▲ 10th %-ile	$60	$180	$280	$360
■ median	$100	$280	$410	$520
◆ 90th %-ile	$170	$420	$600	$740

We invited comment on the provider and supplier cost impact assessment, including the start-up investment and ongoing annual operating costs considered.

Comment: Commenters expressed concern that the ACO infrastructure costs, including start-up and first year operating costs, presented in the proposed rule were low. Furthermore, the commenters referenced a study by the American Hospital Association (AHA) estimating start-up investment and ongoing annual operating costs as more accurately reflecting the associated costs of participating in the Medicare Shared Savings Program.

Response: The AHA study presented estimates much higher than those utilized in this RIA and the independent GAO study. Their estimates focused on two prototypes. The first prototype included a 200 bed, 1 hospital system, with 80 primary care providers and 150 specialists. The second prototype included a 1,200 bed, 5 hospital system, with 250 primary care providers and 500 specialists.

The overall estimates in the AHA study reflect an all inclusive cost structure well beyond the minimum requirements of the Medicare Shared Savings Program and the anticipated average participating ACO. As a result, the AHA study identifies three notes of caution relative to its findings. First, depending on the organization and circumstances of the ACO, some of the costs identified in the study may have already been incurred or attributable to purposes other than ACO-related development. Second, AHA acknowledges that the four case studies presented are not a large sample size from which to estimate costs. Third, their research work was conducted before the Medicare Shared Savings Program proposed rule was published and does not reflect the policies for the program put forth in either the proposed rule or this final rule. Furthermore, the study acknowledges that at the time of their research, the nature of ACOs and the process of developing them had not been standardized. In addition, the reporting requirements for ACOs had not yet been disclosed. Lastly, the study concludes that these estimates should be used as ''early indicators,'' and ''certainly not as definitive measures for ACOs in the Medicare Shared Savings Program.'' We agree with the limitations of the study and as a result, we continue to believe that the independent GAO analysis provided on the Medicare PGP Demonstration and the analysis to support the advanced payment model offer a more closely aligned benchmark for assessing the start-up investment and ongoing annual operating costs associated with participation in the Medicare Shared Savings Program under the policies established in this final rule.

4. Impact 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 nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.0 to $34.5 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/sites/default/files/Size_Standards_Table.pdf.*

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 drafted the rules and regulations accordingly in order to minimize costs and burden on such entities as well as maximize their opportunity to participate. The Shared Savings Program is designed to encourage individual physicians and small physician practices to integrate with other such practices as well as larger entities to create ACOs. Small entities will both be allowed and encouraged to participate in the Shared Savings Program, provided they have a minimum of 5,000 assigned beneficiaries, thereby realizing economic benefits through the utilization of enhanced and efficient systems of care and care coordination. Examples of increased economic benefits as a result of participating in this program include shared savings from this program, as well as qualifying for financial incentives from other CMS programs, such as PQRS, EHR, and e-Rx incentive payments. Therefore, a solo, small physician practice or other small entity may realize these 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.

Again, we note that the Shared Savings Program is a voluntary program and payments for individual items and services would continue to be made on a FFS basis. This final rule will have a significant impact on a substantial number of small entities and we present more detailed analysis on these impacts, including costs and benefits to small entities and alternative policy considerations throughout this RIA. However, as detailed in this RIA, the total median bonus payments will exceed the average costs borne by participating in the Shared Savings Program. As a result, this regulatory impact section, together with the remainder of the preamble, constitutes the Final Regulatory Flexibility Analysis.

In addition, section 1102(b) of the Social Security 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 created the regulations such that rural hospitals will have the opportunity to participate and, where possible, be provided incentives to encourage participation, such as shared savings and the opportunity to qualify for financial incentives from other CMS programs, such as the EHR Incentive Program. As detailed in this RIA, the estimated aggregate median impact of bonus payments to participating ACOs more than exceeds the estimated average costs borne by voluntarily participating in the Shared Savings Program.

E. Alternatives Considered

This final rule contains a range of policies. Many tenets of the program are statutorily mandated and thus allow for little, if any, flexibility in the rulemaking process. Where there was flexibility, we made our policy decisions regarding alternatives based on a balance between creating the least possible negative impact on the stakeholders affected by the program and satisfactorily fitting the vision of the program within given operational constraints.

For example, while the Affordable Care Act mandates that an ACO be large enough to care for a minimum of 5,000 assigned beneficiaries, as is described in the preamble, we are adopting a sliding minimum percentage and confidence interval for the savings threshold based on the size of an ACO. This policy is a balance of protecting the program from paying out savings based on random variation, while allowing attainable thresholds for smaller ACOs and thus encouraging participation from various sized entities.

The preceding preamble provides descriptions of the various statutory provisions that are addressed in this final rule, identifies those policies when discretion has been allowed and exercised, presents the rationales for our final policies and, where relevant, alternatives that were considered. An important alternative involves making adjustments to an ACO's benchmark for changes in FFS price adjustments (such as the geographic practice cost index (GPCI) under the PFS and hospital wage index). Such price changes regularly occur and often impact counties or other localities in magnitudes that can significantly differ from the national average. If, for example, operating cost payments are reduced for section 508 of the MMA hospitals (as will occur under current law at the end of FY 2011) then ACO-attributed claims incurred in a section 508 of the MMA hospital would exhibit significant price decreases which could lead to shared savings payments unrelated to real improvements in ACO efficiency. Absent such adjustments, these statutory changes will impact the comparison of actual expenditures and the benchmark. As we have previously noted, the statute provides authority for adjustment to the benchmark for ''such other factors as the Secretary determines appropriate,'' and while there is no similar authority under section 1899(d) of the Act to adjust actual expenditures during a performance year for ''such other factors'' we considered using our authority under section 1899(i) of the Act to make such adjustments to the determination of actual expenditures. Although this potentially beneficial but operationally complex policy is not included in this final rule, we note that such adjustment may be explored by pilots designed within the Innovation Center and could potentially inform future rulemaking for this program. However, we do note, that we are using our authority under sections 1899(d) and (i) of the Act to make adjustments to remove IME and DSH payments from both benchmark and performance expenditures, constituting a partial step toward a bonus formula that responds to improvements in utilization rather than differences in price between performance and benchmark expenditures.

The proposed rule received numerous comments calling for a method for risk adjustment to take into account changes in the health status of the population between the benchmark period and performance year. Options were considered for the final rule that could reflect such changes in beneficiary characteristics without rewarding ACOs for more complete and accurate HCC coding of their assigned patient population than would occur for a comparable group of beneficiaries receiving care outside an ACO. Therefore a method was chosen for stratifying the benchmark by four distinct beneficiary eligibility categories that each share a unique expenditure profile: ESRD, disabled, aged dual-eligible beneficiaries and aged non-dual-eligible beneficiaries. The benchmark will be normalized to the mix of

beneficiaries aligned across the four strata in a given performance year, improving the fidelity of the updated benchmark to the beneficiary characteristics in such performance year. In addition, adjustments will be made to account for changes in severity and case mix for newly assigned beneficiaries utilizing CMS–HCC prospective scores. Demographic factors alone would be used to adjust for changes for continuously assigned beneficiaries in order to avoid rewarding ACOs for more complete and accurate diagnosis coding, unless this populations HCC risk score declines in which case it will be reset at the lower rate. Such combined method for accounting for shifts in the characteristics of the assigned population is expected to reduce variation in expenditure growth relative to the benchmark and also to mitigate the incentive for ACOs to reduce services to high-risk patients in order to compare favorably against a static benchmark.

Comments also frequently discussed the limited reward presented by the proposed rule relative to the costs that providers estimated they would incur for infrastructure and operation as an ACO under the program. Many elements of the final rule respond directly to this concern, including the removal of required risk in the third year under Track 1, the addition of first-dollar sharing in Track 1, the increased sharing caps for both tracks, the removal of the 25 percent withhold on shared-savings dollars, and the reduction in operational burdens such as the number of quality measures to be reported. All described changes likely improve the business-case for ACOs to join the program, whether in terms of reduced burden or enhanced benefit of participation. However, our modeling of these changes' impact on the Medicare program indicated that the removal of the 2 percent threshold is the most significant change that directly affects the more favorable program sharing arrangement. Raising the sharing caps is not likely to affect shared savings payments for even the highest-performing ACOs. The withholds were also expected to have minimal direct financial impact since an ACO incurring a withhold—and therefore generating measured savings in year 1 or 2—would be unlikely to incur a penalty in a following year of the agreement period (and would be even less likely to fail to repay the penalty in such rare case). Requiring risk in the third year was not anticipated to generate significant additional penalty dollars, since it would most likely cause ACOs experiencing difficulty meeting their benchmarks to terminate their agreements prior to that third year rather than face likely penalties. As a result, removing this requirement is expected to enhance program participation without negatively impacting the estimated net Federal savings.

Finally, a key design element with potential to significantly affect the impact of the program involves the method for establishing quality standards. We propose aggregating the quality domain scores into a single overall ACO score used to calculate the ACO's final sharing rate for purposes of determining shared savings or shared losses as described in section II.F. of this final rule. We would average all domain scores for an ACO together equally to calculate the overall quality score used to calculate the ACO's final sharing rate as previously described. We also considered a variety of scoring methodologies that would have differing incentives for improving clinical outcomes such as: Scoring measures individually under a method that would weigh all measures equally as well as weighing quality measures by their clinical importance. In addition to the performance score approach that rewards ACOs for better quality with larger percentages of shared savings as modeled in this analysis, we could use a threshold approach that allows any ACO that meets minimum standards for the quality measures to realize the full shared savings. However, our final policy encourages continuous quality improvement since ACOs that score higher on quality get to keep a higher percentage of the savings they generate compared to ACOs that perform lower on quality.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table 12, we have prepared an accounting statement showing the classification of transfers, benefits and costs associated with the provisions of this final rule.

TABLE 12—ACCOUNTING STATEMENT: ESTIMATED TRANSFERS, BENEFITS AND COSTS

[CYs 2012–2015]

Category	Transfers			
Annualized monetized transfers	Year dollar	Units discount rate		Notes
	2011	7%	3%	
	Primary Estimate	−$110.08 million	−$112.85 million	These estimates represent the range of annualized impacts on the Medicare Program (net bonus payments) for CYs 2012–2015.
	90th Percentile Estimate	$11.02 million	$10.45 million.	
	10th Percentile Estimate	−$233.92 million	−$238.76 million.	
From/To	Federal Government to ACO Providers			
Category	COSTS			
Year Dollar: 2011: Primary Estimate	Primary Estimate	$112.2 million	$112.5 million	Estimated aggregate average start-up investment and ongoing annual operating costs based on the mean ACO participation rate for CYs 2012 through 2015.

TABLE 12—ACCOUNTING STATEMENT: ESTIMATED TRANSFERS, BENEFITS AND COSTS—Continued

[CYs 2012–2015]

Category	Transfers			
Annualized monetized transfers	Year dollar	Units discount rate		Notes
	2011	7%	3%	
Category	BENEFITS			
Qualitative Benefits	Improved healthcare delivery and communication to beneficiaries through patient centered-care.			

G. Conclusion

As a result of this final rule, the median estimate of the financial impact from implementation of the Shared Savings Program, for CYs 2012 through 2015, is a net savings (after bonus payments) of $470 million. Although this is the ''best estimate'' for the financial impact of the Shared Savings Program during CYs 2012 through 2015, a relatively wide range of possible outcomes exists. Overall, 90 percent of the stochastic trials resulted in net program savings, and the remaining 10 percent represented cost increases. The 90th and 10th percentiles of the estimate distribution show net savings of $940 million and $0 million, respectively, suggesting a 10 percent likelihood that the actual impact would exceed $940 million and a 10 percent likelihood that the actual impact would result in a negative net Federal savings (that is, a net Federal cost). In the extreme scenarios, the results were as large as $2.0 billion in savings or $1.1 billion 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 annual operating cost of $451 million for CYs 2012 through 2015. Lastly, we estimate an aggregate median impact of $1.31 billion in bonus payments to participating ACOs in the Shared Savings Program for CYs 2012 through 2015. The 10th and 90th percentiles of the estimate distribution, for the same time period, yield bonus payments to ACOs of $890 million and $1.9 billion, respectively. Therefore, the total median ACO bonus payments of $1.31 billion during CYs 2012 through 2015 coupled with the aggregate average start-up investment and ongoing annual operating cost of $451 million, incurred by the mean participation rate of ACOs in the Shared Savings Program during the same time period, yields a benefit-cost ratio of 2.9.

Overall, we assumed greater participation by ACOs under the policies contained in this final rule due to the greater generosity and the longer agreement period, as well as the full agreement period with a one-sided option. The longer agreement period also amplified our saving and cost estimates from what they would have been in a 3-year program. This resulted in total bonuses increasing dramatically, while penalties decreased due to these changes.

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, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV by adding part 425 to read as follows:

PART 425—MEDICARE SHARED SAVINGS PROGRAM

Sec.

Subpart A—General Provisions

425.10 Basis and scope.
425.20 Definitions.

Subpart B—Shared Savings Program Eligibility Requirements

425.100 General.
425.102 Eligible providers and suppliers.
425.104 Legal entity.
425.106 Shared governance.
425.108 Leadership and management.
425.110 Number of ACO professionals and beneficiaries.
425.112 Required processes and patient-centeredness criteria.
425.114 Participation in other shared savings initiatives.

Subpart C—Application Procedures and Participation Agreement

425.200 Agreement with CMS.
425.202 Application procedures.
425.204 Content of the application.
425.206 Evaluation procedures for applications.
425.208 Provisions of participation agreement.
425.210 Application of agreement to ACO participants, ACO providers/suppliers, and others.
425.212 Changes to program requirements during the agreement term.
425.214 Managing changes to the ACO during the agreement.
425.216 Actions prior to termination.
425.218 Termination of the agreement by CMS.
425.220 Termination of an agreement by the ACO.
425.222 Reapplication after termination.

Subpart D—Program Requirements and Beneficiary Protections

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Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 425.10 Basis and scope.

(a) *Basis.* This part implements section 1899 of the Act by establishing a shared savings program that promotes accountability for a patient population, coordinates items and services under Medicare parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. The regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare.

(b) *Scope.* This part sets forth the following:

(1) The eligibility requirements for an ACO to participate in the Medicare Shared Savings Program (Shared Savings Program).

(2) Application procedures and provisions of the participation agreement.

(3) Program requirements and beneficiary protections.

(4) The method for assigning Medicare fee-for-service beneficiaries to ACOs.

(5) Quality performance standards, reporting requirements, and data sharing.

(6) Payment criteria and methodologies (one-sided model and two-sided model).

(7) Compliance monitoring and sanctions for noncompliance.

(8) Reconsideration review process.

§ 425.20 Definitions.

As used in this part, unless otherwise indicated—

Accountable care organization (ACO) means a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a Taxpayer Identification Number (TIN), and is formed by one or more ACO participants(s) that is(are) defined at § 425.102(a) and may also include any other ACO participants described at § 425.102(b).

ACO participant means an individual or group of ACO provider(s)/supplier(s), that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants that is required under § 425.204(c)(5).

ACO professional means an ACO provider/supplier who is either of the following:

(1) A physician legally authorized to practice medicine and surgery by the State in which he 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—

(1) Is a provider (as defined at § 400.202 of this chapter) or a supplier (as defined at § 400.202 of this chapter);

(2) Is enrolled in Medicare;

(3) Bills for items and services it furnishes 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

(4) Is included on the list of ACO providers/suppliers that is required under § 425.204(c)(5).

Agreement period means 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.

Antitrust Agency means the Department of Justice or Federal Trade Commission.

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 a physician who is an ACO provider/supplier so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care.

At-risk beneficiary means, but is not limited to, a beneficiary who—

(1) Has a high risk score on the CMS–HCC risk adjustment model;

(2) Is considered high cost due to having two or more hospitalizations or emergency room visits each year;

(3) Is dually eligible for Medicare and Medicaid;

(4) Has a high utilization pattern;

(5) Has one or more chronic conditions.

(6) Has had a recent diagnosis that is expected to result in increased cost.

(7) Is entitled to Medicaid because of disability; or

(8) Is diagnosed with a mental health or substance abuse disorder.

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's participant during the most recent prior calendar year.

Covered professional services has the same meaning given these terms under section 1848(k)(3)(A) of the Act.

Critical access hospital (CAH) has the same meaning given this term under § 400.202 of this chapter.

Eligible professional has the meanings given this term under section 1848(k)(3)(B) of the Act.

Federally qualified health center (FQHC) has the same meaning given to this term under § 405.2401(b) of this chapter.

Hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

Marketing materials and activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, data sharing opt out letters, mailings, social media, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program. The following beneficiary communications are not marketing materials and activities: Certain informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO, its ACO participants, or its ACO providers/suppliers; materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues; educational information on specific medical conditions (for example, flu shot reminders), written referrals for health care items and services, and materials or activities that do not constitute ''marketing'' under 45 CFR 164.501 and 164.508(a)(3)(i).

Medicare fee-for-service beneficiary means an individual who is—

(1) Enrolled in the original Medicare fee-for-service program under both parts A and B; and

(2) Not enrolled in any of the following:

(i) A MA plan under part C.

(ii) An eligible organization under section 1876 of the Act.

(iii) A PACE program under section 1894 of the Act.

Medicare Shared Savings Program (Shared Savings Program) means the program, established under section 1899 of the Act and implemented in this part.

Newly assigned beneficiary means a beneficiary that is assigned in the current performance year who was neither assigned to nor receives a primary care service from any of the ACO's participants during the most recent prior calendar year.

One-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under subpart G of this part.

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise noted in the ACO's agreement. For an ACO with a start date of April 1, 2012 or July 1, 2012, the ACO's first performance year is defined as 21 months and 18 months, respectively.

Physician means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

Physician Quality Reporting System (PQRS) means the quality reporting system established under section 1848(k) of the Act.

Primary care physician means a physician who has a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine, or, for services furnished in an FQHC or RHC, a physician included in an attestation by the ACO as provided under § 425.404.

Primary care services mean the set of services identified by the following HCPCS codes:

(1) 99201 through 99215.

(2) 99304 through 99340, and 99341 through 99350, G0402 (the code for the Welcome to Medicare visit), G0438 and G0439 (codes for the annual wellness visits);

(3) Revenue center codes 0521, 0522, 0524, 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

Quality measures means the measures defined by the Secretary, under section 1899 of the Act, to assess the quality of care furnished by an ACO, such as measures of clinical processes and outcomes, patient and, where practicable, caregiver experience of care and utilization.

Reporting period, for purposes of subpart F of this part, means the calendar year from January 1 to December 31.

Rural health center (RHC) has the same meaning given to this term under § 405.2401(b).

Shared losses means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, above the applicable benchmark, it must repay to CMS. An ACO's eligibility for shared losses will be determined for each performance year. For an ACO requesting interim payment, shared losses may result from the interim payment calculation.

Shared savings means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, below the applicable benchmark, it is eligible to receive payment for from CMS. An ACO's eligibility for shared savings will be determined for each performance year. For an ACO requesting interim payment, shared savings may result from the interim payment system calculation.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

Two-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under subpart G of this part.

Subpart B—Shared Savings Program Eligibility Requirements

§ 425.100 General.

(a) Under the Shared Savings Program, ACO participants may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO that meets the criteria specified in this part. The ACO must become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) ACOs that meet or exceed a minimum savings rate established under § 425.604 or § 425.606, meet the minimum quality performance standards established under § 425.500, and otherwise maintain their eligibility to participate in the Shared Savings Program under this part are eligible to receive payments for shared savings under subpart G.

(c) ACOs that operate under the two-sided model and meet or exceed a minimum loss rate established under § 425.606 must share losses with the Medicare program under subpart G of the part.

§ 425.102 Eligible providers and suppliers.

(a) The following ACO participants or combinations of ACO participants are eligible to form an ACO that may apply to participate in the Shared Savings Program:

(1) ACO professionals in group practice arrangements.

(2) Networks of individual practices of ACO professionals.

(3) Partnerships or joint venture arrangements between hospitals and ACO professionals.

(4) Hospitals employing ACO professionals.

(5) CAHs that bill under Method II (as described in § 413.70(b)(3) of this chapter).

(6) RHCs.

(7) FQHCs.

(b) Other ACO participants that are not identified in paragraph (a) of this section are eligible participate through an ACO formed by one or more of the ACO participants identified in paragraph (a) of this section.

§ 425.104 Legal entity.

(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 purposes of the following:

(1) Receiving and distributing shared savings.

(2) Repaying shared losses or other monies determined to be owed to CMS.

(3) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.

(4) Fulfilling other ACO functions identified in this part.

(b) An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants.

§ 425.106 Shared governance.

(a) *General rule.* An ACO must maintain an identifiable governing body with 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, report on quality and cost measures, and coordinate care.

(b) *Responsibilities of the governing body and its members.* (1) The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities as described in this part.

(2) The governing body must have a transparent governing process.

(3) The governing body members must have a fiduciary duty to the ACO and must act consistent with that fiduciary duty.

(4) The governing body of the ACO must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent ACO participants.

(5) If the ACO is an existing entity, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies the other requirements of this section.

(c) *Composition and control of the governing body.* (1) The ACO must 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 representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(3) At least 75 percent control of the ACO's governing body must be held by ACO participants.

(4) The governing body members may serve in a similar or complementary manner for an ACO participant.

(5) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraphs (c)(2) and (c)(3) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries.

(d) *Conflict of interest.* The ACO governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must—

(1) Require each member of the governing body to disclose relevant financial interests; and

(2) Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise.

(3) The conflict of interest policy must address remedial action for members of the governing body that fail to comply with the policy.

§ 425.108 Leadership and management.

(a) An ACO must have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(b) The ACO's operations must 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.

(c) Clinical management and oversight must be managed by a senior-level medical director who is a physician and one of its ACO providers/suppliers, who is physically present on a regular basis at any clinic, office, or other location participating in the ACO, and who is a board-certified physician and licensed in a State in which the ACO operates.

(d) Each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure the ACO's likely success.

(1) Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant and ACO provider/supplier to achieve the ACO's mission under the Shared Savings Program.

(2) A meaningful commitment can be shown when an ACO participant or ACO provider/supplier agrees to comply with and implement the ACO's processes required by § 425.112 and is held accountable for meeting the ACO's performance standards for each required process.

(e) CMS retains the right to give consideration to an innovative ACO with a management structure not meeting paragraphs (b) through (c) of this section.

§ 425.110 Number of ACO professionals and beneficiaries.

(a)(1) The ACO must include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under subpart E of this part. The ACO must have at least 5,000 assigned beneficiaries.

(2) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries specified in paragraph (a)(1) of this section if the number of beneficiaries historically assigned to the ACO participants in each of the three years before the start of the agreement period, using the assignment methodology in subpart E of this part, is 5,000 or more.

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO will be issued a warning and placed on a CAP.

(1) While under the CAP, the ACO remains eligible for shared savings and losses during that performance year and its MSR will be set at a level consistent with the number of assigned beneficiaries.

(2) If the ACO's assigned population is not returned to at least 5,000 or more by the end of next performance year, the ACO's agreement will be terminated and the ACO will not be eligible to share in savings for that performance year.

§ 425.112 Required processes and patient-centeredness criteria.

(a) *General.* (1) An ACO must—

(i) Promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care;

(ii) Adopt a focus on patient centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams; and

(iii) Have defined processes to fulfill these requirements.

(2) An ACO must have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program, which must include the defined processes included in paragraphs (b)(1) through (4) of this section.

(3) For each process specified in paragraphs (b)(1) through (4) of this section, the ACO must—

(i) Explain how it will require ACO participants and ACO providers/suppliers to comply with and implement each process (and subelement thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process; and

(ii) Explain how it will employ its internal assessments of cost and quality of care to improve continuously the ACO's care practices.

(b) *Required processes.* The ACO must define, establish, implement, evaluate, and periodically update processes to accomplish the following:

(1) Promote evidence-based medicine. These processes must cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.

(2) Promote patient engagement. These processes must address the following areas:

(i) Compliance with patient experience of care survey requirements in § 425.500.

(ii) Compliance with beneficiary representative requirements in § 425.106.

(iii) A process for evaluating the health needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.

(A) In its plan to address the needs of its population, the ACO must describe how it intends to partner with community stakeholders to improve the health of its population.

(B) An ACO that has a stakeholder organization serving on its governing body will be deemed to have satisfied the requirement to partner with community stakeholders.

(iv) Communication of clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

(v) Beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities;

(vi) Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

(3) Develop an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics that enables the ACO to monitor, provide feedback, and evaluate its ACO participants and ACO provider(s)/supplier(s) performance and to use these results to improve care over time.

(4) Coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers. The ACO must—

(i) Define its methods and processes established to coordinate care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO); and

(ii) As part of its application, the ACO must:

(A) Submit a description of its individualized care program, along with a sample individual 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.

(B) Describe additional target populations that would benefit from individualized care plans. Individual care plans must take into account the community resources available to the individual.

§ 425.114 Participation in other shared savings initiatives.

(a) ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in the independence at home medical practice pilot program under section 1866E of the Act, a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings.

(b) CMS will review and deny an ACO's application if any ACO participants are participating in another Medicare initiative that involves shared savings payments.

(c) CMS will determine an appropriate method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs or initiatives, including initiatives involving dually eligible beneficiaries, when such other shared savings programs have an assignment methodology that is different from the Shared Savings Program.

Subpart C—Application Procedures and Participation Agreement

§ 425.200 Agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than three years.

(b) *Term of agreement.* (1) *For 2012.* For applications that are approved to participate in the Shared Savings Program for 2012, the start date for the agreement will be one of the following:

(i) April 1, 2012 (term of the agreement is 3 years and 9 months).

(ii) July 1, 2012 (term of the agreement is 3 years and 6 months).

(2) For 2013 and all subsequent years—

(i) The start date is January 1 of that year; and

(ii) The term of the agreement is 3 years.

(c) *Performance year.* (1) Except as specified in paragraphs (b)(1)(i) and (ii) of this section, the ACO's performance year under the agreement is the 12 month period beginning on January 1 of each year during the term of the agreement unless otherwise noted in its agreement.

(2) For an ACO with a start date of April 1, 2012 or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(d) During each calendar year of the agreement period, including the partial year associated with start dates specified in paragraph (b)(1)(i) and (ii) of this section, ACOs must submit measures in the form and manner required by CMS.

§ 425.202 Application procedures.

(a) *General rules.* (1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by CMS by the deadline established 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 application is accurate, complete, and truthful.

(3) An ACO that seeks to participate in the Shared Savings Program and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of their application with the Antitrust Agencies.

(b) *Condensed application form.* PGP demonstration sites applying to participate in the Shared Savings Program will have an opportunity to complete a condensed application form.

(c) *Application review.* (1) CMS determines whether an applicant satisfies the requirements of this part and is qualified to participate in the Shared Savings Program.

(2) CMS approves or denies applications accordingly.

§ 425.204 Content of the application.

(a) *Accountability for beneficiaries.* As part of its application and participation agreement, the ACO must certify that the ACO, its ACO participants, and its ACO providers/suppliers have agreed to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) *Disclosure of prior participation.* (1) The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Medicare Shared Savings Program under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO.

(2) The ACO must specify whether the related ACO agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary.

(3) If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the

cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the agreement.

(c) *Eligibility.* (1) As part of its application, an ACO must submit to CMS the following supporting materials to demonstrate that the ACO satisfies the eligibility requirements set forth in subpart B of this part:

(i) Documents (for example, participation agreements, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers'/suppliers' rights and obligations in and representation by the ACO, including 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 evidenced-based clinical guidelines.

(ii) 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.

(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 including administrative and clinical leaders specifically noted in § 425.108.

(iv) Evidence that the governing body is an identifiable body, that the governing body is comprised of representatives of the ACO's participants, and that the ACO participants have at least 75 percent control of the ACO's governing body.

(v) Evidence that the governing body includes a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(vi) A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the ACO's agreement with CMS becomes effective.

(2) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

(i) Charters.

(ii) By-laws.

(iii) Articles of incorporation.

(iv) Partnership agreement.

(v) Joint venture agreement.

(vi) Management or asset purchase agreements.

(vii) Financial statements and records.

(viii) Resumes and other documentation required for leaders of the ACO.

(3) If an ACO requests an exception to the—

(i) Governing body requirements in § 425.106, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries or both; or

(ii) Leadership and management requirements in § 425.108, the ACO must describe how its alternative leadership and management structure will be capable of accomplishing the ACO's mission.

(4)(i) An ACO must certify that it is recognized as a legal entity in the State, Federal or Tribal area in which it was established and that it is authorized to conduct business in each State or Tribal area in which it operates.

(ii) An ACO formed among multiple, independent ACO participants must provide evidence in its application that it is a legal entity separate from any of the ACO participants.

(5) The ACO must provide CMS with such information regarding its ACO participants and its ACO providers/suppliers participating in the program as is necessary to implement the program.

(i) The ACO must submit a list of all ACO participants and their Medicare-enrolled TINs.

(A) For each ACO participant, the ACO must submit a list of the ACO providers/suppliers and their provider identifier (for example, NPI) and indicate whether the ACO provider/supplier is a primary care physician as defined in § 425.20.

(B) The list specified in paragraph (c)(5)(i)(A) of this section must be updated in accordance with § 425.302(d).

(ii) ACOs must also submit any other specific identifying information as required by CMS in the application process.

(iii) If the ACO includes an FQHC or RHC as an ACO participant, it must also do the following:

(A) Indicate the TINs, organizational NPIs, and other identifying information for its participant FQHCs or RHCs or both, as well as NPIs and other identifying information for the physicians that directly provide primary care services in the participant FQHCs or RHCs or both.

(B) Submit any other specific identifying information for its participant FQHCs or RHCs or both as required by CMS in the application process.

(iv) The ACO must certify the accuracy of this information.

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must describe the following:

(1) How it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its ACO participants and ACO providers/suppliers.

(2) How the proposed plan will achieve the specific goals of the Shared Savings Program.

(3) How the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

(e) *Selection of track and option for interim payment calculation.*

(1) As part of its application, an ACO must specify whether it is applying to participate in Track 1 or Track 2 (as described in § 425.600).

(2)(i) An ACO applying to participate in the program with a start date of April 1, 2012 or July 1, 2012, has the option of requesting an interim payment calculation based on the financial performance for its first 12 months of program participation and quality performance for CY 2012.

(ii) An ACO must request interim payment calculation as part of its application to participate in the Shared Savings Program.

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay losses for which it may be liable, and any other monies determined to be owed upon first performance year reconciliation.

(i) As part of its application, an ACO that is applying to participate under the two-sided model of the Shared Savings Program or requesting an interim payment calculation under the one-sided model must submit for CMS approval documentation that it is capable of repaying losses or other monies determined to be owed upon first year reconciliation.

(ii) The documentation specified in paragraph (f)(1)(i) of this section must include details supporting the adequacy of the mechanism for repaying losses, or other monies determined to be owed

upon first year reconciliation, 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 either on expenditures for the most recent performance year or expenditures used to establish the benchmark.

(2) 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.

(3) An ACO participating under the two-sided model must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk.

§ 425.206 Evaluation procedures for applications.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an ACO's application on the basis of the information contained in and submitted with the application.

(2) CMS notifies applicant ACOs when the application is incomplete and provide an opportunity to submit information to complete the application. Applications remaining incomplete by the application due date will be denied.

(b) *Notice of determination.* (1) CMS notifies in writing each applicant ACO of its determination to approve or deny the ACO's application to participate in the Shared Savings Program.

(2) If CMS denies the application, the notice will indicate that the ACO is not qualified to participate in the Shared Savings Program, specify the reasons why the ACO is not so qualified, and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

§ 425.208 Provisions of participation agreement.

(a) *General rules.* (1) Upon being notified by CMS of its approval to participate in the Shared Savings Program, an executive of that ACO who has the ability to legally bind the ACO must sign and submit to CMS a participation agreement.

(2) Under the participation agreement the ACO must agree to comply with the provisions of this part in order to participate in the Shared Savings Program.

(b) *Compliance with laws.* 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 agree, or to comply with all applicable laws including, but not limited to, the following:

(1) Federal criminal law.

(2) The False Claims Act (31 U.S.C. 3729 *et seq.*).

(3) The anti-kickback statute (42 U.S.C. 1320a–7b(b)).

(4) The civil monetary penalties law (42 U.S.C. 1320a–7a).

(5) The physician self-referral law (42 U.S.C. 1395nn).

(c) *Certifications.* (1) The ACO must agree, as a condition of participating in the program and receiving any shared savings payment, that an individual with the authority to legally bind the ACO will certify the accuracy, completeness, and truthfulness of any data or information requested by or submitted to CMS, including, but not limited to, the application form, participation agreement, and any quality data or other information on which CMS bases its calculation of shared savings payments and shared losses.

(2) Certifications must meet the requirements at § 425.302.

§ 425.210 Application of agreement to ACO participants, ACO providers/suppliers, and others.

(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.

(b) All 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 this part, including, but not limited to, those specified in the participation agreement with CMS.

§ 425.212 Changes to program requirements during the agreement term.

(a)(1) ACOs are subject to all statutory changes that become effective during the term of their participation agreement.

(2) ACOs are subject to all regulatory changes with the exception of the following program areas:

(i) Eligibility requirements concerning the structure and governance of ACOs.

(ii) Calculation of sharing rate.

(iii) Beneficiary assignment.

(b) In those instances where there are changes in law or regulations, the ACO will be required to submit to CMS for review and approval, as a supplement to its original application, an explanation detailing how it will modify its processes to address these changes in law or regulations.

(c) If an ACO does not modify its processes to address a change in law or regulations, it will be placed on a CAP. If the ACO fails to effectuate the necessary modifications while under the CAP, the ACO will be terminated from the Shared Savings Program using the procedures in § 425.218.

(d) An ACO will be permitted to terminate its agreement, in those instances where Shared Savings Program statutory and regulatory standards are established during the agreement period which the ACO believes will impact its ability to continue to participate in the Shared Savings Program.

§ 425.214 Managing changes to the ACO during the agreement.

(a)(1) During the term of the participation agreement, an ACO may add or remove ACO participants or ACO providers/suppliers (identified by TINs and NPIs).

(2) An ACO must notify CMS within 30 days of such an addition or removal.

(3) The ACO's benchmark, risk scores, and preliminary prospective assignment may be adjusted for this change at CMS' discretion.

(b) ACOs must notify CMS within 30 days of any significant change. A ''significant change'' occurs when an ACO is no longer able to meet the eligibility or program requirements of this Part.

(c) Upon receiving an ACO's notice of a significant change described in paragraph (b) of this section, CMS reevaluates the ACO's eligibility to continue to participate in the Shared Savings Program and may request additional documentation. CMS may make a determination that includes one of the following:

(1) The ACO may continue to operate under the new structure.

(2) The ACO structure is so different from the initially approved ACO that it must terminate its agreement and submit a new application for participation.

(3) The ACO no longer meets the eligibility criteria for the program and its participation agreement must be terminated.

(4) CMS and the ACO may mutually decide to terminate the agreement.

§ 425.216 Actions prior to termination.

(a) *Pre-termination actions.* (1) If CMS concludes that termination of an ACO from the Shared Savings Program is warranted, CMS may take one or more

of the following actions prior to termination of the ACO from the Shared Savings Program.

(i) Provide a warning notice to the ACO regarding noncompliance with one or more program requirements.

(ii) Request a CAP from the ACO.

(iii) Place the ACO on a special monitoring plan.

(2) Nothing in this part, including the actions set forth in paragraph (a)(1) of this section, negates, diminishes, or otherwise alters the applicability of other laws, rules, or regulations, including, but not limited to, the Sherman Act (15 U.S.C. 1 *et seq.*), the Clayton Act (15 U.S.C. 12), and the Federal Trade Commission Act (15 U.S.C. 45 *et seq.*).

(b) *Corrective action plans.* (1) The ACO must submit a CAP for CMS approval by the deadline indicated on the notice of violation.

(i) The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to the ACO's activities or both correct any deficiencies and comply with all applicable Shared Savings Program requirements.

(ii) The ACO's performance will be monitored and evaluated during and after the CAP process.

(2) CMS may terminate the ACO's agreement if the ACO fails to submit, obtain approval for, or implement a CAP, or fails to demonstrate improved performance upon completion of the CAP.

§ 425.218 Termination of the agreement by CMS.

(a) *General.* CMS may terminate the participation agreement with an ACO when an ACO, the ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the Shared Savings Program under this part.

(b) *Grounds for termination by CMS.* CMS may terminate the participation agreement for reasons including, but not limited to the following:

(1) Non-compliance with eligibility and other requirements described in this part.

(2) The imposition of sanctions or other actions taken against the ACO by an accrediting organization, State, Federal or local government agency leading to inability of the ACO to comply with the requirements under this part.

(3) Violations of the physician self-referral prohibition, civil monetary penalties (CMP) law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.

(c) CMS may immediately terminate a participation agreement without taking any of the pre-termination actions set forth in § 425.216.

(d) *Notice of termination by CMS.* CMS notifies an ACO in writing of its decision to terminate the participation agreement.

§ 425.220 Termination of an agreement by the ACO.

(a) *Notice of termination.* An ACO must provide at least 60 days advance written notice to CMS and its ACO participants of its decision to terminate the participation agreement and the effective date of its termination.

(b) *Payment consequences of early termination.* The ACO will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement.

§ 425.222 Re-application after termination.

(a) 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.

(b) To be eligible to participate in the Shared Savings Program after a previous termination, the ACO must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.

(c) An ACO under the one-sided model whose agreement was previously terminated may reenter the program only under the two-sided model unless it was terminated less than half way through its agreement under the one-sided model in which case it will be allowed to re-enter the one-sided model. An ACO under the two-sided model whose agreement was terminated may only re-apply for participation in the two-sided model.

Subpart D—Program Requirements and Beneficiary Protections

§ 425.300 Compliance plan.

(a) The ACO must have a compliance plan that includes at least the following elements:

(1) A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body.

(2) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(3) A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.

(4) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(5) A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

(b)(1) ACOs that are existing entities may use the current compliance officer if the compliance officer meets the requirements set forth in paragraph (a)(1) of this section.

(2) An ACO's compliance plan must be in compliance with and be updated periodically to reflect changes in law and regulations.

§ 425.302 Program requirements for data submission and certifications.

(a) *Requirements for data submission and certification.*

(1) The ACO, its ACO participants, its ACO providers/suppliers or individuals or other entities performing functions or services related to ACO activities must submit all data and information, including data on measures designated by CMS under § 425.500, in a form and manner specified by CMS.

(2) *Certification of data upon submission.* With respect to data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, an individual with the authority to legally bind the individual or entity submitting such data or information must certify the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge information and belief.

(3) *Annual certification.* At the end of each performance year, an individual with the legal authority to bind the ACO must certify to the best of his or her knowledge, information, and belief—

(i) That the ACO, its ACO participants, its ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are in compliance with program requirements; and

(ii) The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of a shared savings payment or the amount of shared losses or other monies owed to CMS.

(b) [Reserved]

§ 425.304 Other program requirements.

(a) *Beneficiary inducements.* (1) ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Consistent with the provisions of paragraph (a)(1) of this section and subject to compliance with all other applicable laws and regulations, ACO, ACO participants and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to beneficiaries if there is a reasonable connection between the items and services and the medical care of the beneficiary and the items or services are preventive care items or services or advance a clinical goal for the beneficiary, including 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.

(b) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers will be reviewed during the Shared Savings Program application 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.

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(c) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

(d) *Required reporting of NPIs and TINs.* (1) The ACO must maintain, update, and annually furnish to CMS at the beginning of each performance year and at other such times as specified by CMS the list of each ACO participant's TIN and ACO providers/supplier's NPI that is required to be submitted under § 425.204(c)(5)(i).

(2) The ACO must notify CMS within 30 days of any changes to the list of NPIs and TINs.

§ 425.306 Participation agreement and exclusivity of ACO participant TINs.

(a) For purposes of the Shared Savings Program, each ACO participant TIN is required to commit to a participation agreement with CMS.

(b) Each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one Medicare Shared Savings Program ACO for purposes of Medicare beneficiary assignment. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to one Medicare Shared Savings Program ACO.

§ 425.308 Public reporting and transparency.

For purposes of the Shared Savings Program, each ACO must publicly report the following information regarding the ACO in a standardized format as specified by CMS:

(a) Name and location.

(b) Primary contact.

(c) Organizational information including all of the following:

(1) Identification of ACO participants.

(2) Identification of participants in joint ventures between ACO professionals and hospitals.

(3) Identification of the members of its governing body.

(4) Identification of associated committees and committee leadership.

(d) Shared savings and losses information, including:

(1) Amount of any shared savings performance payment received by the ACO or shared losses owed to CMS.

(2) 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.

(e) Results of patient experience of care survey and claims based measures. Quality measures reported using the GPRO web interface will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

§ 425.310 Marketing requirements.

(a) *File and use.* Marketing materials and activities, as defined in § 425.20, may be used or conducted five business days following their submission to CMS if—

(1) The ACO certifies compliance with all the marketing requirements under this section; and

(2) CMS does not disapprove the marketing materials or activities.

(b) *Deemed approval.* (1) Marketing materials and activities are deemed approved after expiration of the initial 5 day review period specified in paragraph (a) of this section.

(2)(i) CMS may issue written notice of disapproval of marketing materials and activities at any time, including after the expiration of the initial 5 day review period.

(ii) The ACO, ACO participant, ACO provider/supplier, or another individual or entity performing functions or services related to ACO activities as applicable, must discontinue use of any marketing materials or activities disapproved by CMS.

(c) *Marketing requirements.* Marketing materials and activities must meet all of the following:

(1) Use template language developed by CMS, if available.

(2) Not be used in a discriminatory manner or for discriminatory purposes.

(3) Comply with § 425.304(a) regarding beneficiary inducements.

(4) Not be materially inaccurate or misleading.

(d) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

§ 425.312 Notification to beneficiaries of participation in shared savings program.

(a) ACO participants must do all of the following:

(1) Notify beneficiaries at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program.

(2) Post signs in their facilities to notify beneficiaries that their ACO providers/suppliers are participating in the Shared Savings Program.

(3) Make available standardized written notices regarding participation in an ACO and, if applicable, data opt-out. Such written notices must be provided by the ACO participants in settings in which beneficiaries receive primary care services.

(b)(1) ACOs have the option of notifying beneficiaries on the preliminary prospective assignment list and quarterly assignment list provided to the ACO under § 425.704(d).

(2) ACOs choosing this option must use the standardized written notice developed by CMS.

(c) The beneficiary notifications under this section meet the definition of marketing materials and activities under § 425.20 and therefore must meet all applicable marketing requirements described in § 425.310.

§ 425.314 Audits and record retention.

(a) *Right to audit.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree, that the CMS, DHHS, the Comptroller General, the Federal Government or their designees have the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities that pertain to all of the following:

(1) The ACO's compliance with Shared Savings Program.

(2) The quality of services performed and determination of amount due to or from CMS under the participation agreement.

(3) The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

(4) If as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination.

(b) *Maintenance of records.* An ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree to the following:

(1) To maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

(2) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the ACO at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, in which case ACOs must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(c) *Responsibility of the ACO.* Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS, including the requirements set forth in this section.

(d) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

§ 425.316 Monitoring of ACOs.

(a) *General rule.* (1) In order to ensure that the ACO continues to satisfy the eligibility and program requirements under this part, CMS monitors and assesses the performance of ACOs, their ACO participants, and ACO providers/suppliers.

(2) CMS employs a range of methods to monitor and assess the performance of ACOs, ACO participants, and ACO providers/suppliers, including but not limited to any of the following, as appropriate:

(i) Analysis of specific financial and quality measurement data reported by the ACO as well as aggregate annual and quarterly reports.

(ii) Analysis of beneficiary and provider complaints.

(iii) Audits (including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits, on-site compliance reviews).

(b) *Monitoring ACO avoidance of at-risk beneficiaries.* (1) CMS may use one or more of the methods described in paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggesting that an ACO has avoided at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with beneficiaries or the ACO and its ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities, in order to substantiate cases of beneficiary avoidance.

(2)(i) CMS, at its sole discretion, may take any of the pre-termination actions set forth in § 425.216(a)(1) or immediately terminate, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries.

(ii) If CMS requires the ACO to submit a CAP, the ACO will—

(A) Submit a CAP that addresses actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities cease avoidance of at-risk beneficiaries.

(B) Not receive any shared savings payments during the time it is under the CAP.

(C) Not be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at risk beneficiaries).

(iii) CMS will re-evaluate the ACO during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries. The ACO will be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP implementation period.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under § 425.500. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, in addition to actions set forth at § 425.216 and § 425.218, CMS will take the following actions:

(1) The ACO may be given a warning for the first time it fails to meet the minimum attainment level in one or more domains as determined under § 425.502 and may be subject to a CAP. CMS, may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(2) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet quality performance standards in the following year, the agreement will be terminated.

(3)(i) If an ACO fails to report one or more quality measures or fails to report completely and accurately on all measures in a domain, CMS will request that the ACO submit—

(A) The required measure data;

(B) Correct the data;

(C) Provide a written explanation for why it did not report the data completely and accurately; or

(D) A combination of the submission requirements in paragraphs (c)(3)(i)(A) through (c)(3)(i)(C) of this section.

(ii) If ACO still fails to report, fails to report by the requested deadline, or does not provide a reasonable explanation for not reporting, the ACO will be terminated immediately.

(4) An ACO that exhibits a pattern of inaccurate or incomplete reporting of the quality performance measures, or fails to make timely corrections following notice to resubmit, may be terminated.

(5) An ACO will not qualify to share in savings in any year it fails to report fully and completely on the quality performance measures.

Subpart E—Assignment of Beneficiaries

§ 425.400 General.

(a)(1)(i) A Medicare fee-for-service beneficiary is assigned to an ACO when the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402.

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined.

(2)(i) Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on most recent data available.

(ii) Assignment will be updated quarterly based on the most recent 12 months of data.

(iii) Final assignment is determined after the end of each performance year, based on data from the performance year.

(b) Beneficiary assignment to an ACO is for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable under subpart F of this part, and for determining whether an ACO has achieved savings under subpart G of this part, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPCS codes, G codes, or revenue center codes as indicated in the definition of primary care services under § 425.20.

§ 425.402 Basic assignment methodology.

(a) 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 provider/supplier of that ACO:

(1)(i) Identify all primary care services rendered by primary care physicians during one of the following:

(A) The most recent 12 months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment).

(B) The performance year (for purposes of final assignment).

(ii) The beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all the primary care physicians who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are—

(A) ACO providers/suppliers in any other ACO; and

(B) Not affiliated with any ACO and identified by a Medicare-enrolled TIN.

(2) The second step considers the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not had a primary care service rendered by any primary care physician, either inside 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 all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by—

(i) All ACO professionals who are ACO providers/suppliers in any other ACO; and

(ii) Other physicians, nurse practitioners, physician assistants, clinical nurse specialists who are unaffiliated with an ACO and are identified by a Medicare-enrolled TIN.

(b) [Reserved]

§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.

CMS assigns beneficiaries to ACOs based on services furnished in FQHCs or RHCs or both consistent with the general assignment methodology in § 425.402, with two special conditions:

(a) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.

(b) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service if the—

(1) NPI of a physician included in the attestation is reported on the claim as the attending provider; and

(2) Claim includes a HCPCS or revenue center code that meets the definition of primary care services under § 425.20.

Subpart F—Quality Performance Standards and Reporting

§ 425.500 Measures to assess the quality of care furnished by an ACO.

(a) *General.* CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible for shared savings.

(b) *Selecting measures.* (1) CMS selects the measures designated to determine an ACO's success in promoting the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(2) CMS designates the measures for use in the calculation of the quality performance standard.

(3) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(c) ACOs must submit data on the measures determined under paragraph (b) of this section according to the method of submission established by CMS.

(d) *Patient experience of care survey.* For performance years beginning in 2014 and for subsequent performance years, ACOs must select a CMS-certified vendor to administer the survey and report the results accordingly.

(e) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO.

(1) In an audit, the ACO will provide beneficiary medical records data if requested by CMS.

(2) The audit will consist of three phases of medical record review.

(3) If, at the conclusion of the third audit process there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate exists.

(f) Failure to report quality measure data accurately, completely, and timely (or to timely correct such data) may subject the ACO to termination or other sanctions, as described in § 425.216 and § 425.218.

§ 425.502 Calculating the ACO quality performance score.

(a) *Establishing a quality performance standard.* CMS designates the quality performance standard in each performance year.

(1) For the first performance year of an ACO's agreement, CMS defines the quality performance standard at the level of complete and accurate reporting for all quality measures.

(2) During subsequent performance years, the quality performance standard will be phased in such that the ACO must continue to report all measures but the ACO will be assessed on performance based on the minimum attainment level of certain measures.

(b) *Establishing a performance benchmark and minimum attainment level for measures.* (1) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures.

(2) Contingent upon data availability, performance benchmarks are defined by CMS based on national Medicare fee-for-service rates, national MA quality measure rates, or a national flat percentage.

(3) The minimum attainment level is set at 30 percent or the 30th percentile of the performance benchmark.

(c) *Methodology for calculating a performance score for each measure.* (1) Performance below the minimum attainment level for a measure will receive zero points for that measure.

(2) Performance equal to or greater than the minimum attainment level for a measure will receive points on a sliding scale based on the level of performance.

(3) Those measures designated as all or nothing measures will receive the maximum available points if all criteria are met and zero points if one or more of the criteria are not met.

(4) Performance at or above 90 percent or the 90th percentile of the performance benchmark earns the maximum points available for the measure.

(d) *Establishing quality performance requirements for domains.* (1) CMS groups individual quality performance standard measures into four domains:

(i) Patient/care giver experience.

(ii) Care coordination/Patient safety.

(iii) Preventative health.

(iv) At-risk population.

(2) To satisfy quality performance requirements for a domain:

(i) The ACO must report all measures within a domain.

(ii) ACOs must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take the actions describe in § 425.216(c).

(iii)(A) If the ACO achieves the minimum attainment level for at least one measure in each of the four domains, and also satisfies the requirements for realizing shared savings under subpart G of this part, the ACO may receive the proportion of those shared savings for which it qualifies.

(B) If an ACO fails to achieve the minimum attainment level on all measures in a domain, it will not be eligible to share in any savings generated.

(e) *Methodology for calculating the ACO's overall performance score.* (1) CMS scores individual measures and determines the corresponding number of points that may be earned based on the ACO's performance.

(2) CMS adds the points earned for the individual measures within the domain and divides by the total points available for the domain to determine the domain score.

(3) Domains are weighted equally and scores averaged to determine the ACO's overall performance score and sharing rate.

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System.

(a) *Physician quality reporting system.* (1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using the GPRO web interface established by CMS, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System incentive under the Shared Savings Program.

(2)(i) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of receiving an incentive payment under the Physician Quality Reporting System.

(ii) Under the Shared Savings Program, an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under Subpart F of this part during the reporting period according to the method of submission established by CMS under the Shared Savings Program in order to receive a Physician Quality Reporting

System incentive under the Shared Savings Program.

(3) If ACO providers/suppliers who are eligible professionals within an ACO qualify for a Physician Quality Reporting System incentive payment, each ACO participant TIN, on behalf of its ACO supplier/provider participants who are eligible professionals, will receive an incentive, for those years an incentive is available, based on the allowed charges under the Physician Fee Schedule for that TIN.

(4) ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot earn a Physician Quality Reporting System incentive outside of the Medicare Shared Savings Program.

(5) The Physician Quality Reporting System incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the Secretary's estimate of the ACO's eligible professionals' total Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31, for years 2012 through 2014.

(b) [Reserved]

§ 425.506 Electronic health records technology.

(a) ACOs, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure.

(b) As part of the quality performance score, the quality measure regarding EHR adoption will be measured based on a sliding scale.

(c) Performance on this measure will be weighted twice that of any other measure for scoring purposes and for determining compliance with quality performance requirements for domains.

Subpart G—Shared Savings and Losses

§ 425.600 Selection of risk model.

(a) For its initial agreement period, an ACO may elect to operate under one of the following tracks:

(1) *Track 1.* Under Track 1, the ACO operates under the one-sided model (as described under § 425.604 of this part) for the agreement period.

(2) *Track 2.* Under Track 2, the ACO operates under the two-sided model (as described under § 425.606), sharing both savings and losses with the Medicare program for the agreement period.

(b) For subsequent agreement periods, an ACO may not operate under the one-sided model.

(c) An ACO experiencing a net loss during the initial agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also 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.

§ 425.602 Establishing the benchmark.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures.* In computing an ACO's fixed historical benchmark that is adjusted for historical growth and beneficiary characteristics, including health status, CMS determines 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 agreement period using the ACO participants' TINs identified at the start of the agreement period. CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) This calculation considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) 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 benchmark year in order to minimize variation from catastrophically large claims.

(5)(i) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(ii) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures in BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) The ACO's benchmark may be adjusted for the addition and removal of ACO participants or ACO providers/suppliers during the term of the agreement period.

(b) *Updating the benchmark.* CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of 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.

(1) CMS updates this fixed benchmark 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 using data from CMS' Office of the Actuary.

(2) To update the benchmark, CMS makes expenditure calculations for separate categories 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.

(c) *Resetting the benchmark.* An ACO's benchmark will be reset at the start of each agreement period.

§ 425.604 Calculation of savings under the one-sided model.

(a) *Savings determination.* 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 below the applicable updated benchmark determined under § 425.602.

(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 population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS will adjust for changes in severity and case mix in 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 adjustments for separate categories 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 rate (MSR).* CMS uses a sliding scale, based on the number of beneficiaries assigned to the ACO under subpart E of this part, to establish the MSR for an ACO participating under the one-sided model. The MSR under the one-sided model for an ACO based on the number of assigned beneficiaries is as follows:

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
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	

(c) *Qualification for shared savings payment.* In order to qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined 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 the one-sided model will receive a shared savings payment of up to 50 percent of all savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 of this part (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 the one-sided model may not exceed 10 percent of its updated benchmark.

(f) *Notification of savings.* 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.

§ 425.606 Calculation of shared savings and losses under the two-sided model.

(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 the two-sided model, 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 will adjust 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) To qualify for shared savings under the two-sided model, 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 2 percent.

(2) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must be at least 2 percent above its updated benchmark costs for the year.

(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 of this part, 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 the two-sided model will receive a shared savings payment of up to 60 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 of this part (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 the two-sided model may not exceed 15 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 § 425.606(d) (that is, 1 minus the final shared savings rate determined under § 425.606(d) of this part); and

(2) May not exceed 60 percent.

(g) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark as determined under § 425.602:

(1) 5 percent in the first performance year of participation in a two-sided model under the Shared Savings Program.

(2) 7.5 percent in the second performance year.

(3) 10 percent in the third and any subsequent performance year.

(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.

§ 425.608 Determining first year performance for ACOs beginning April 1 or July 1, 2012.

(a) For April 1 and July 1, 2012 starters, first year (defined as 21 and 18 months respectively) performance will be based on an optional interim payment calculation (based on the ACO's first 12 months of participation) and a final reconciliation at the end of the ACO's first performance year. Unless stated otherwise, for purposes of the interim payment calculation and first year reconciliation, the methodology under subpart E of this part for assigning beneficiaries and the methodology described in § 425.602 through § 425.606 for calculating shared savings and losses will apply, and quality performance will be assessed as described in subpart F of this part.

(b) In the interim payment calculation, based on the ACO's first 12 months of performance—

(1) CMS compares the first 12 months of per capita beneficiary expenditures to a historical benchmark updated for the period which includes the ACO's first 12 months of participation, taking into account changes in health status and demographics; and

(2) Quality performance is based on GPRO quality data reported for CY 2012.

(c)(1) The interim payment calculation is reconciled with the ACO's performance for its complete first performance year, defined as 21 months for April 1, 2012 starters and 18 months for July 1, 2012 starters.

(2) The first year reconciliation takes into account expenditures spanning the entire 21 or 18 months of the first performance year.

(3) First performance year expenditures are summed over beneficiaries assigned in two overlapping 12 month assignment windows.

(i) The first window will be the first 12 months used for interim payment calculation.

(ii) The second window will be CY2013.

(4) Expenditures for the first performance year are the sum of aggregate expenditure dollars accounting for the ACO's first 6 or 9 months of performance within CY 2012 for beneficiaries assigned for the interim payment calculation and aggregate dollars calculated for CY2013 for beneficiaries assigned for CY 2013.

(5) Adjustments for health status and demographic changes are performed as described in § 425.604 through § 425.606 with the following exceptions:

(i) Beneficiaries from the CY2013 assignment window are identified as continuously assigned or newly assigned relative to the previous calendar year.

(ii) The adjustment factor identified for purposes of the interim payment calculation is applied to the 6 months or 9 months of the ACO's first performance year that lie within CY2012.

(6) The updated benchmark, stated in aggregate dollars, is the sum of the interim updated benchmark for the average fraction of expenditures incurred in the latter 6 or 9 months of CY 2012 and an updated aggregate benchmark representing CY 2013.

(7) A savings percentage (based on a comparison of summed expenditures to summed updated benchmark dollars) for the ACO's 18 or 21 month performance year is compared to the ACO's MSR or MLR. The reconciled amount of the shared savings or losses owed to or by the ACO for the performance year is net of any interim payments of shared savings or losses.

(8) Quality performance for the first year reconciliation is based on complete and accurate reporting, of all required quality measures, for CYs 2012 and 2013.

(d) An ACO with a start date of April 1, 2012 or July 1, 2012 has the option to request an interim payment calculation based on quality and financial performance for its first 12 months of program participation. As required under § 425.204(f), the ACO requesting an interim payment calculation must have a mechanism in place to pay back the interim payment if final reconciliation determines an overpayment.

(e) Unless otherwise stated, program requirements which apply in the course of a performance year apply to the interim payment calculation and first year reconciliation.

Subpart H—Data Sharing With ACOs

§ 425.700 General rules.

(a) CMS shares aggregate reports with the ACO.

(b) CMS shares beneficiary identifiable data with ACOs on the condition that the ACO, its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data use agreement described in this subpart.

(c) The ACO must not limit or restrict appropriate sharing of medical record data with providers and suppliers both within and outside the ACO in accordance with applicable law.

§ 425.702 Aggregate reports.

CMS shares aggregate reports with ACOs as follows:

(a) Aggregate reports are shared at the start of the agreement period based on beneficiary claims data used to calculate the benchmark, and each quarter thereafter during the agreement period.

(b) These aggregate reports include, when available, the following information, deidentified in accordance with 45 CFR 164.514(b):

(1) Aggregated metrics on the assigned beneficiary population.

(2) Utilization and expenditure data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

(c)(1) 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, will provide the ACO with information regarding preliminarily prospectively assigned beneficiaries whose data was used to generate the aggregate data reports under paragraphs (a) and (b) of this section. The information includes the following:

(i) Beneficiary name.

(ii) Date of birth.

(iii) HICN.

(iv) Sex.

(2) In its request for these data, the ACO must certify that it is seeking the following information:

(i) As a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct 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.

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

§ 425.704 Beneficiary-identifiable data.

Subject to providing the beneficiary with the opportunity to decline data sharing as described in this § 425.708, and subject to having a valid DUA in place, CMS, upon the ACO's request for the data for purposes of evaluating the performance of its ACO participants or its ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, will provide the ACO with beneficiary identifiable claims data for preliminary prospective assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant upon whom assignment is based during the agreement period.

(a) If an ACO wishes to receive beneficiary identifiable claims data, it must sign a DUA and it must submit a formal request for data. ACOs may request data as often as once per month.

(b) The ACO must certify that it is requesting claims data about either of the following:

(1) Its own patients, as a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct 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.

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

(c) The use of identifiers and claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries with primary care services at the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries.

(d) To ensure that beneficiaries have a meaningful opportunity to decline having their claims data shared with the ACO, the ACO may only request claims data about a beneficiary if—

(1) The beneficiary name appears on the preliminary prospective assignment list found on the initial or quarterly aggregate report, or has received primary care services from an ACO participant upon whom assignment is based (under Subpart E of this part), during the agreement period.

(2) The beneficiary has been notified in writing how the ACO intends to use beneficiary identifiable claims data in order to improve the quality of care that is furnished to the beneficiary and, where applicable, coordinate care offered to the beneficiary; and

(3) The beneficiary did not exercise the opportunity to decline having his/her claims data shared with the ACO as provided in § 425.708.

(e) At the ACO's request, CMS continues to provide ACOs with updates to the requested beneficiary identifiable claims data, subject to beneficiary's opportunity to decline data sharing under § 425.708.

(f) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in § 425.710 is a condition of an ACO's participation in the Shared Savings Program.

§ 425.706 Minimum necessary data.

(a) ACOs must limit their identifiable data requests to the minimum necessary to accomplish a permitted use of the data. The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Procedure code.
(3) Gender.
(4) Diagnosis code.
(5) Claim ID.
(6) The from and through dates of service.
(7) The provider or supplier ID.
(8) The claim payment type.
(9) Date of birth and death, if applicable.
(10) TIN.
(11) NPI.

(b) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Prescriber ID.
(3) Drug service date.
(4) Drug product service ID.
(5) Quantity dispensed.
(6) Days supplied.
(7) Brand name.
(8) Generic name.
(9) Drug strength.
(10) TIN.
(11) NPI.
(12) Indication if on formulary.
(13) Gross drug cost.

§ 425.708 Beneficiaries may decline data sharing.

(a) Before requesting claims data about a particular beneficiary, the ACO must inform the beneficiary that it may request personal health information about the beneficiary for purposes of its care coordination and quality improvement work, and give the beneficiary meaningful opportunity to decline having his/her claims information shared with the ACO.

(b) ACOs may contact preliminarily prospective assigned beneficiaries. in writing to request data sharing.

(1) If these beneficiaries do not decline within 30 days after the letter is sent, the ACO may request identifiable claims data from CMS.

(2) These beneficiaries must also be provided a form explaining the beneficiary's opportunity to decline data sharing as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(c) For beneficiaries that have a primary care service office visit with an ACO participant who provides primary care services, the ACO must supply the beneficiaries with a written notification explaining their opportunity to decline data sharing. The form must be provided to each beneficiary as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(d) The requirements specified in paragraphs (a) through (c) of this section do not apply to the initial identifiable data points that CMS provides to ACOs under § 425.702(d).

(e) CMS does not share beneficiary identifiable claims data relating to treatment for alcohol and substance abuse in accordance with 42 CFR 290dd–2 and the implementing regulations at 42 CFR part 2.

(f) The provisions of this section relate only to the sharing of Medicare claims data between the Medicare program and the ACO under the Shared Savings Program and are in no way intended to impede existing or future data sharing under other authorities.

§ 425.710 Data use agreement.

(a)(1) Before receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. Under the DUA, the ACO must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the statutory and regulatory requirements of the Shared Savings Program.

(2) If the ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the DUA, it will no longer be eligible to receive data under subpart H of this part, may be terminated from the Shared Savings Program under § 425.218, and may be subject to additional sanctions and penalties available under the law.

(b) [Reserved]

Subpart I—Reconsideration Review Process

§ 425.800 Preclusion of administrative and judicial review.

(a) There is no reconsideration, appeal, or other administrative or judicial review of the following determinations under this part:

(1) The specification of quality and performance standards under § 425.500 and § 425.502.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.502.

(3) The assignment of Medicare fee-for-service beneficiaries under Subpart E of this part.

(4) The determination of whether an 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 Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO under § 425.602, § 425.604, and § 425.606.

(5) 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.

(6) The termination of an ACO for failure to meet the quality performance standards established under § 425.502.

(b) [Reserved]

§ 425.802 Request for review.

(a) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official.

(1) An ACO that wants to request reconsideration review by a CMS reconsideration official must submit a written request by an authorized official for receipt by CMS within 15 days of the notice of the initial determination.

(i) If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(ii) Failure to submit a request for reconsideration within 15 days will result in denial of the request for reconsideration.

(2) The reconsideration review may be held 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) An ACO that requests a reconsideration review for termination will remain operational throughout the review process.

§ 425.804 Reconsideration review process.

(a) *Acknowledgement of reconsideration review request.* The reconsideration official sends an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(1) Review procedures.

(2) Procedures for submission of evidence including format and timelines.

(3) Date, time, and location of the review.

(b) *Burden of proof, standard of proof, and standards of review.* The burden of proof is on the ACO to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with the

requirements of this part or applicable statutory authority.

(c) *Reconsideration official.* The reconsideration official is an independent CMS official who did not participate in the initial determination that is being reviewed.

(d) *Time and place of hearing.* The reconsideration official may, on his or her own motion, or at the request of CMS or the ACO, change the time and place for the reconsideration review, but must give CMS and the ACO notice of the change.

(e) *Evidence.* (1) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless otherwise requested by the reconsideration official.

(2) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by the applicable deadline and in the requested format.

(3) All evidence submitted by the ACO and CMS, in preparation for the reconsideration review will be shared with the other party to the hearing.

(f) The reconsideration official will notify CMS and the ACO of his or her recommendation.

§ 425.806 On-the-record review of reconsideration official's recommendation by independent CMS official.

(a)(1) If CMS or the ACO disagrees with the recommendation of the reconsideration official, it may request an on the record review of the initial determination and recommendation by an independent CMS official who was not involved in the initial determination or the reconsideration review process.

(2) In order to request an on-the-record review, CMS or the ACO must submit an explanation of why it disagrees with the recommendation by the timeframe and in the format indicated in the reconsideration official's recommendation letter.

(b) The on-the-record review process is based only on evidence presented during the reconsideration review.

(c) The independent CMS official considers the recommendation of the reconsideration official and makes a final agency determination.

§ 425.808 Effect of independent CMS official's decision.

(a) The decision of the independent CMS official is final and binding.

(b) The reconsideration review process under this subpart must not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

§ 425.810 Effective date of decision.

(a) If the initial determination denying an ACO's application to participate in the Shared Savings Program is upheld, the application will remain denied based on the effective date of the original notice of denial.

(b) If the initial determination to terminate an agreement with an ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

(c) If the initial determination to terminate an ACO is reversed, the ACO is reinstated into the Shared Savings Program, retroactively back to the original date of termination.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 6, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 19, 2011.

Kathleen Sebelius,

Secretary.

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